Effects of Electronic Cigarette Flavors on Abuse Liability in Smokers (P3 TASTE)

Dr. Caroline Cobb, Associate Professor of Psychology & Dr. Andrew Barnes, Associate Professor of Health Behavior and Policy

Initial Approval:
2/15/2023

Most recent approval: 12/17/2024

THIS STUDY WAS NOT REQUIRED TO SUBMIT THE STATISTICAL ANALYSIS SECTION TO THE IRB. THE SECTION WAS ADDED TO THIS REPORT AND TAKEN FROM THE GRANT. OUR PROCESSES HAVE BEEN UPDATED AND STUDIES APPROVED IN 2024 WOULD BE REQUIRED.

Study Identification

1. * **Select the Principal Investigator:**
   Caroline Cobb Amey

2. * **Study Title:**
   Effects of Electronic Cigarette Flavors on Abuse Liability in Smokers (P3-Taste)

3. * **Is this a student or trainee project in which activities will be carried out by that individual under your supervision (for example, dissertation or degree-required projects):**
   - ○ Yes
   - ● **No**

4. * **Please select the primary department or center that this study is being conducted under:**
   Psychology

5. **Select the VCU IRB numbers assigned to studies that are:**
   1. **Associated with this study**
   2. **Research registries this study will utilize**
   3. **Previously submitted versions of this study (closed, withdrawn, auto-withdrawn studies)**

ID	Title	PI
HM20002567	CSTP Overall Screening and Registry	Caroline Cobb Amey

6. **Select all individuals who are permitted to edit the IRB protocol and should be copied on communications (study staff will be entered later). These individuals will be referred to as protocol editors:**

Last Name	First Name	E-Mail	Phone	Mobile
Amey	Caroline Cobb	cobbco@vcu.edu		
Barnes	Andrew	abarnes3@vcu.edu		
Carrico		carricoma@vcu.edu		
Imran	Rabia	imranr@vcu.edu		
Ogunleye	Elizabeth	ogunleyee@vcu.edu		

7. * **Select one of the following that applies to the project (selection will branch to new pages):**
   Note: VCU IRB offers guidance for many types of studies, including secondary data analysis studies, internet research, registries, EFIC, HUD, and Emergency Use protocols.
   See *https://research.vcu.edu/human_research/guidance.htm*
   - ● **Research Project or Clinical Investigation [*most exempt, expedited, and full board research studies]**
   - ○ Exception from Informed Consent (EFIC) for Planned Emergency Research
   - ○ Humanitarian Use of Device for Treatment or Diagnosis
   - ○ Humanitarian Use of Device for Clinical Investigation
   - ○ Emergency Use of Investigational Drug, Biologic or Device
   - ○ Treatment Use (Expanded Access to Investigational Product for Treatment Use)

- ○ Center or Institute Administrative Grant Review
- ○ Request for Not Human Subject Research Determination (i.e. request a letter confirming that IRB review is not required)

Federal Regulations

1. * **Is this a FDA regulated study?**

FDA regulated research includes all clinical investigations involving a test article and a human subject(s) that has been submitted for approval to the FDA or may be submitted in the future. Check Yes if
- **the study involves an IND/IDE, abbreviated IDE, IND/IDE exemption, HUD, expanded access, or is otherwise subject to 21 CFR 56,**
- **the study involves a test article being administered or dispensed to subjects NOT according to a clinicians' medical judgment but rather, per the study protocol, OR**
- **the study does not involve a test article but intends to provide safety or efficacy data to the FDA.**

(●) **Yes**
( ) No

2. * **Indicate the FDA regulated product(s) this study involves:**

[ ] Drug
[ ] Medical Device
[ ] Biologic
[ ] Dietary Supplement
[ ] Food/Food Additive
[ ] Color Additive
[ ] Electronic Products for Human Use (radiation producing)
[x] **Tobacco Product**
[x] **Other**

3. * **If "Other" selected above, provide description:**
The study products used in this study include those that fall under FDA's regulatory authority. Some products have been authorized by the FDA and others are awaiting decision-making and may be authorized and/or not authorized for marketing by the FDA. Findings from this study are intended to help inform FDA tobacco product regulations.

4. * **Is this study supported by the Department of Defense (DoD):**

( ) Yes
(●) **No**

5. * **Check if any of the following funding sources apply to this research (including Direct and/or Indirect funding):**

[ ] Department of Education
[ ] Department of Justice
[ ] Environmental Protection Agency
[x] **None of the above**

IRB Panel Setup

1. * **To which IRB is this study being submitted for review?**
   - (●) **VCU IRB**
   - ( ) WCG IRB
   - ( ) NCI Central IRB
   - ( ) Advarra IRB
   - ( ) Other IRB

2. * **Is this study transitioning to review by another IRB?**
   - ( ) Yes - transitioning from VCU IRB to an external IRB (WCG, CIRB, Other)
   - ( ) Yes - transitioning from an external IRB (WCG, CIRB, Other) to VCU IRB
   - (●) **No or not applicable**

HM20025464 - Caroline Cobb Amey
Effects of Electronic Cigarette Flavors on Abuse Liability in Smokers (P3-Taste)

Review Setup

1. * **Select which study type best describes the majority of the study. Your response will help determine which IRB panel should review this.**
   - ○ Bio-Medical Research
   - ● **Social/Behavioral/Education (SBE) Research**

2. * **Which option(s) best describe the way(s) this study's procedures will be conducted? (Select all that apply.) This information may be used by the IRB in triaging studies during an emergency.**
   - ☑ **In-person interactions / interventions with participants**
   - ☐ Remote interactions / interventions with participants
   - ☐ Secondary data/specimen analyses with or without contact with study participants

3. * **Would it be possible to convert in-person activities in your study to remote if there is an approved contingency protocol?**
   No, not possible to convert to remote activities

4. * **Does this study involve greater than minimal risk:**
   ○ Yes ● **No**

5. * **Review type requested: (subject to IRB approval):**
   - ● **Full Board**
   - ○ Expedited
   - ○ Exempt

6. * **Is this study initiated by a VCU investigator or a sponsor:**
   - ● **VCU Investigator initiated**
   - ○ Sponsor or industry initiated

The IRB has determined that the selected types of anticipated individual and social benefit apply to this study

The below information is read-only to investigators, and the categories are set by the IRB during review. All categories will appear blank until the IRB has made a determination. If a category is not checked, it does not apply to this study. This information may be used by the IRB in triaging studies during an emergency situation.
Possible or minimal direct benefit to the community
Scientific benefit

Initial Setup Complete

Protocol Progress:
● **INITIAL SETUP**
② BACKGROUND, RATIONALE & GOALS
③ RESEARCH PLAN
④ CONSENT PLAN
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Background, Rationale and Goals

1. * **Describe the study's background and what is currently known from the scientific literature, including citations, or upload a citation list in document upload. Use lay language whenever possible.**

   FDA's "public health standard" requires consideration of how tobacco product regulation will influence risks and benefits to tobacco users and non-users. Among other things, FDA must be cognizant of regulatory impact on transitions across tobacco products for current users, including initiation of one product and cessation of another and dual use of both. These issues are particularly salient for e-cigarettes (ECIGs) due to their increasing popularity. Addressing them through regulation will be challenging because ECIGs are an evolving product class with great variability in liquid nicotine concentration, device power, rate of nicotine emission (i.e., nicotine flux), and flavors (USDHHS, 2016; Talih et al., 2017). These factors can influence ECIG abuse liability, the likelihood that an ECIG will maintain persistent use and dependence (e.g., Carter et al., 2009). Regulatory action intended to influence population-level ECIG use must account for these factors.

   If FDA is to understand how tobacco regulation will influence the risks and benefits to cigarette smokers, exclusive ECIG users and dual users of ECIGs and tobacco cigarettes, it may learn much from robust scientific methods that predict the likely population-level impact of potential regulatory action in these populations. Indeed, if FDA had scientific methods that could predict these population-level outcomes, these methods could be used to generate data to guide the development of potential regulation. Our goal is to provide these methods to FDA.

   To do so, we use behavioral economic indices of abuse liability to examine to hypotheses related to three potential regulatory actions: limiting nicotine concentration (ongoing study; completed study), constraining nicotine flux (nicotine yield/unit time; ongoing study), and reducing flavor availability (the current study). We then use results from clinical lab studies described here, along with results from other studies, to generate predictions about how these potential regulatory actions might impact the population, and then test our predictions at the population level (in a separate study not described in this protocol).

   Carter LP, Stitzer ML, Henningfield JE, O'Connor RJ, Cummings KM, Hatsukami DK. (2009). Abuse liability assessment of tobacco products including potential reduced exposure products. Cancer Epidemiol Biomarkers Prev. 18(12):3241-62.

   Talih S, Balhas Z, Eissenberg T, Salman R, Karaoghlanian N, El Hellani A, Baalbaki R, Saliba N, Shihadeh A. (2015). Effects of user puff topography, device voltage, and liquid nicotine concentration on electronic cigarette nicotine yield: measurements and model predictions. Nicotine Tob Res. 17(2):150-7. PMC4837998

   USDHHS (2016). E-cigarette Use Among Youth and Young Adults: A Report of the Surgeon General. Atlanta, GA: USDHHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.

2. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
   The purpose of this study is to determine if abuse liability indices will be impacted by varying flavors and ECIG nicotine delivery capability (i.e., nicotine flux) among current combustible cigarette users.

   We will compare abuse liability indices between three FDA authorized ECIG products that vary in nicotine flux (but are all tobacco flavor) and own brand cigarettes. We will also test the influence of ECIG flavor availability (tobacco vs. menthol) within three ECIG product classes.

   We hypothesize that as nicotine flux is lowered, abuse liability indices will be lowered.

   We also hypothesize that across ECIG product classes, abuse liability indices will be higher for menthol-flavored products.

3. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
   Aim 1: Compare the abuse liability of own brand (OB) cigarettes and three FDA-authorized tobacco flavor ECIGs that vary by nicotine flux.

   Aim 2: Test the influence of ENDS flavor availability (tobacco vs. menthol) within each ENDS product class.

4. * **Describe the scientific benefit or importance of the knowledge to be gained:**

   The benefits of this research are of a scientific nature. Specifically, we aim to use study results to inform our understanding of the abuse liability of ECIG liquid characteristics as well as provide information to guide the appropriate regulation of ECIGs.

   In particular, the use of ECIGs has become increasingly popular, especially among individuals aged 18-24. New regulations are being targeted at this age group and need to be tested in this age group before implementation. The overarching theme of the Center for the Study of Tobacco Products is to provide regulators (FDA and others) with a suite of tools that allow them to test regulations before they are implemented to determine if those regulations will have

their intended consequences without causing harm (i.e., unintended consequences). If we cannot study the age group the regulations are targeting, we cannot test potential regulations effectively.

We anticipate long term benefits to the public at large by adding to the limited body of knowledge involving these products among tobacco users.

5. * **Describe any potential for direct benefits to participants in this study:**
None.

6. * **Describe any potential for direct social impact in this study . For example, any engagement with specific communities to respond to community-identified needs, or ways the study will strengthen the well-being of the specific communities if applicable:**
Results from this study will provide a broader public health impact to guide the appropriate regulation of ECIGs. We do not anticipate any direct social impacts in this study.

7. **Upload a supporting citation list if applicable:**

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Informed Consent	P3 TASTE_Informed Consent_CLEAN_1.29.2024.pdf	0.15	2/20/2024 10:22 AM	Rabia Imran	Consent/Assent/Information Sheet	Yes
View	Consent - Tool	P3TASTE_Consent_Presentation_1.29.2024.pptx	0.06	1/30/2024 1:34 PM	Rabia Imran	Consent/Assent/Information Sheet	Yes
View	Social Media Plan	P3-TASTE Social Media Plan_10.2.2023.docx	0.01	10/2/2023 3:29 PM	Caroline Cobb Amey	Recruitment/Advertising	Yes
View	Social Media and Craigslist Ads	P3-TASTE_facebook and craiglist ads_10.2.2023.docx	0.01	10/2/2023 3:29 PM	Caroline Cobb Amey	Recruitment/Advertising	Yes
View	Substance Use Resources Handout	CSTP Substance Use Resources_8.11.2023.docx	0.01	8/11/2023 5:11 PM	Caroline Cobb Amey	Other	Yes
View	Subjective Measures	P3-TASTE-Session Subjective Measures_CLEAN_08.09.2023.doc	0.03	8/11/2023 5:10 PM	Rabia Imran	Research Measure	Yes
View	P3 TASTE Advertisement for CSTP Website	P3 TASTE - CSTP Website Study Description_CLEAN_08.08.2023.docx	0.05	8/11/2023 5:09 PM	Rabia Imran	Recruitment/Advertising	Yes
View	Presession Symptom Questions	P3-Presession symptom Checklist-CLEAN_08.09.2023.docx	0.05	8/11/2023 5:08 PM	Rabia Imran	Research Measure	Yes
View	Baseline Self Report Physio Measures	P3-TASTE_Baseline forms All_CLEAN_8.11.2023.docx	0.06	8/11/2023 5:07 PM	Rabia Imran	Research Measure	Yes
View	Text, Email, Call Scripts	P3-TASTE_Phone_e-mail_text scripts_08.09.2023_CLEAN.docx	0.10	8/11/2023 5:06 PM	Rabia Imran	Study reminders/communications	Yes
View	Referral Program Card Template	P3_Referral program card_06.02.2023_CLEAN.docx	0.03	6/13/2023 1:48 PM	Rabia Imran	Recruitment/Advertising	Yes
View	COVID-19 Questions	COVID_Questions_P3_no longer using.docx	0.02	6/13/2023 1:35 PM	Rabia Imran	Other	Yes
View	P3 Taste_ETM	P3-TASTE_Measures_ETM__no longer using.docx	0.04	6/13/2023 1:35 PM	Rabia Imran	Research Measure	Yes
View	Tobacco Cessation Resources Handout	Cessation_handout_RI_04.29.2021.pdf	0.01	2/1/2023 3:32 PM	Caroline Cobb Amey	Other	Yes
View	U54 Grant Application Without Budget	U54 Grant Application BUDGET PAGES DELETED FOR IRB.pdf	0.01	10/28/2022 2:17 PM	Rabia Imran	Funding Proposal	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	CP-DPT & DPT	P3-TASTE Drug Purchase Tasks_9.2.2022.docx	0.01	10/28/2022 2:03 PM	Rabia Imran	Research Measure	Yes
View	CP-DPT & DPT - Tool	DPT_CDPT presentation_10.28.2022.pptx	0.01	10/28/2022 2:03 PM	Rabia Imran	Research Measure	Yes
View	Subjective Measures - Tool	Subjective Measures presentation_10.28.2022.pptx	0.01	10/28/2022 2:00 PM	Rabia Imran	Research Measure	Yes
View	Barnes Biosketch	P3 Barnes biosketch 06.22.17.FINAL.docx	0.01	10/28/2022 1:55 PM	Rabia Imran	CV/Biosketch	Not Applicable
View	Lipato Biosketch	Lipato Biosketch.pdf	0.01	10/28/2022 1:54 PM	Rabia Imran	CV/Biosketch	Yes
View	Caroline Cobb (Amey) CV	CV_Cobb_August 2022.docx	0.01	10/28/2022 1:54 PM	Rabia Imran	CV/Biosketch	Yes
View	Baseline Discounting Task - MDT	P3_TASTE_Discounting Task_11.7.2018.pdf	0.01	10/28/2022 1:54 PM	Rabia Imran	Research Measure	Yes
View	U54 Project 3 Grant Docs	U54_Project 3 only docs.pdf	0.01	10/28/2022 1:53 PM	Rabia Imran	Funding Proposal	Not Applicable
View	CSTP Parking Map	CSTP Parking Map.docx	0.01	10/28/2022 1:52 PM	Rabia Imran	Other	Not Applicable
View	Criticare HR/BP Manual	Criticare_Vitalcare_506N3_-_Service_manual.pdf	0.01	10/28/2022 1:52 PM	Rabia Imran	Other	Not Applicable
View	Expired Air CO Manual	CO Monitor Manual.pdf	0.01	10/28/2022 1:51 PM	Rabia Imran	Other	Not Applicable
View	Information about Blood Pressure	BP results P3 flux 8.22.2022.docx	0.01	10/28/2022 1:51 PM	Rabia Imran	Study reminders/communications	Yes
View	CSTP Registry Consent and Survey	CSTP Registry Consent Form and Questions.pdf	0.01	10/19/2022 3:27 PM	Caroline Cobb Amey	Other	Not Applicable

Study Population

1. * **Provide the maximum number of individuals that**

   1. May participate in any study interaction or intervention (Including screening, consenting, and study activities)
   AND/OR
   2. You obtain any data/specimens about (regardless of identifiability)

   at VCU and at other sites under the VCU IRB's oversight. See the help text for additional guidance.
   100

2. **If this is a multi-Center Project, what is the maximum anticipated number of subjects across all sites?**
   N/A

3. * **Provide justification for the sample size by explaining how you arrived at the expected number of participants and why this number is adequate for answering the research questions:**
   This study manipulates e-cigarette flavor and nicotine flux systematically, testing the hypothesis that abuse liability will be related directly to flux or flavor among a sample of cigarette smokers. Previous studies using this type of design are limited.

   Thus, we calculated a sample size to achieve a power of >0.80 with α <0.05 and assuming a small effect size (Cohen's f=0.20) and moderate repeated measures correlation (r=0.5) in a repeated measures ANOVA with nicotine flux as within-subjects factors (N=32; GPower).

   In this study, 36 cigarette users will attend the lab for 4 sessions: 1) own brand cigarette (always the first session), 2) NJOY Ace 2.4% nicotine ECIG (Menthol and Classic Tobacco flavor), 3) NJOY Ace 5.0% nicotine ECIG (Menthol and Classic Tobacco flavor), and 4) NJOY Daily ECIG 6% nicotine (Menthol and Extra Rich Tobacco).

   We hypothesize that flux will be positively associated with willingness to pay (drug purchase task) and willingness to substitute e-cigarettes for own brand cigarettes (cross-product drug purchase task), and inversely to price sensitivity (drug purchase task) for all smokers.

   We hypothesize that within class, menthol flavored products will be positively associated with willingness to pay (drug purchase task) and willingness to substitute e-cigarettes for own brand cigarettes (cross-product drug purchase task), and inversely to price sensitivity (drug purchase task) for all smokers.

   It is possible that we would consent up to 100 participants in order to obtain 36 participants who complete the entire study.

4. * **List the study inclusion criteria:**
   All participants must be healthy (determined by self-report), at least 18 years old (verified by photo ID), willing to provide informed consent, and attend the lab. Participants must agree to use designated products according to the study protocol.

   Participants must smoke cigarettes at least 3 days per week and on those days at least 1 cigarette smoked per day.

   Participants must have a 'positive' cotinine cassette result to verify nicotine use.

   Please note that beginning July 1, 2020, per HB1570 Virginia law "Provides an exception to the law prohibiting possession of tobacco products, nicotine vapor products, or alternative nicotine products by a person less than 21 years of age when such possession is part of a scientific study being conducted by an organization for the purpose of medical research to further efforts in cigarette and tobacco use prevention and cessation and tobacco product regulation, provided that such medical research has been approved by an institutional review board pursuant to applicable federal regulations or by a research review committee."

5. * **List the study exclusion criteria:**
   Individuals with the following self-reported current, diagnosed medical condition(s) will be excluded automatically: uncontrolled high blood pressure (via self-report or observed at screening; BP must be less than 160/100), heart-related conditions (e.g., recent heart attack/stroke, coronary heart disease), severe immune system disorders (e.g., HIV/AIDS, multiple sclerosis), respiratory disorders (e.g., COPD, asthma), kidney diseases, liver diseases (e.g., cirrhosis), or seizures.

   Individuals with other self-reported current, diagnosed medical conditions (e.g., diabetes, thyroid disease, lyme disease) will be considered for exclusion after consultation with the PI and medical monitor. We ask a variety of questions about participants' medical conditions that are not necessarily exclusionary in order to be able to consult with

the medical monitor about these conditions. Participants with any medical condition/medication that may affect participant safety, study outcomes, or biomarker data will be excluded based on these consultations.

Individuals with current, diagnosed, psychiatric conditions that are uncontrolled will be excluded. A controlled psychiatric illness is defined as one where the individual is taking medication and/or receiving other treatment (e.g., psychotherapy). In addition, individuals who have been to the ER and/or been hospitalized for a psychiatric condition in the past year will be excluded.

Individuals with past month use of cocaine, opioids, benzodiazepines, and methamphetamine or other illegal substances (other than cannabis) will be excluded. Individuals who report using cannabis greater than 15 days in the past 30 and/or alcohol greater than 25 days in the past 30 days will be excluded.

Participants who choose not to answer questions related to inclusion/exclusion criteria will be excluded.

Participants who indicate their sex assigned at birth is female will be excluded if they are breast-feeding or test positive for pregnancy (by urinalysis) at screening.

Those who intend to quit tobacco/nicotine use in the next 30 days will be excluded and referred to cessation treatment.

6. * **Will individuals with limited English proficiency be included in or excluded from this research?**

- ○ Included
- ● **Excluded - safety concerns if participants are unable to communicate with the study team**
- ○ Excluded - instruments/measures only validated in English
- ○ Excluded - no prospect of direct benefit to individual participants
- ○ Excluded - minimal risk study
- ○ Excluded - lack of budget/resources for translation and interpretation [provide an explanation in next question]
- ○ Excluded - other reason [provide an explanation in next question]

7. **Justify the inclusion and exclusion criteria if you are either targeting, or excluding, a particular segment of the population / community. Provide a description of the group/organization/community and provide a rationale.**

We are excluding individuals (<18 years old) as this group includes children for whom research risks may differ compared those 18 or older. This younger age group is also likely to differ in important ways compared to individuals aged 18 and older including likelihood of residing with a guardian/parent which may impact their response to research questions of interest. We also exclude pregnant/breastfeeding individuals as tobacco/nicotine use is dangerous to a fetus/child. We exclude individuals with certain health conditions that may be exacerbated by tobacco product administration. We also exclude individuals with drug use histories that may raise the risk of participation or affect the quality of data collected in the study.

Background, Rationale & Goals Section Complete

Protocol Progress:
● **INITIAL SETUP**
● **BACKGROUND, RATIONALE & GOALS**
③ RESEARCH PLAN
④ CONSENT PLAN
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Study Procedures

1. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
The purpose of this study is to determine if abuse liability indices will be impacted by varying flavors and ECIG nicotine delivery capability (i.e., nicotine flux) among current combustible cigarette users.

We will compare abuse liability indices between three FDA authorized ECIG products that vary in nicotine flux (but are all tobacco flavor) and own brand cigarettes. We will also test the influence of ECIG flavor availability (tobacco vs. menthol) within three ECIG product classes.

We hypothesize that as nicotine flux is lowered, abuse liability indices will be lowered.

We also hypothesize that across ECIG product classes, abuse liability indices will be higher for menthol-flavored products.

2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
Aim 1: Compare the abuse liability of own brand (OB) cigarettes and three FDA-authorized tobacco flavor ECIGs that vary by nicotine flux.

Aim 2: Test the influence of ENDS flavor availability (tobacco vs. menthol) within each ENDS product class.

3. * **Choose all types of recruitment materials that may be used and upload them below:**
   - [ ] E-mail invitations
   - [ ] Phone Solicitation scripts (i.e. cold calls or random-digit-dialing)
   - [ ] Flyers, Mailed Letters or Newspaper/TV/Radio Ads
   - [ ] TelegRAM announcements
   - [x] **Website text**
   - [ ] Study-specific web sites (provide the design and text)
   - [x] **Social Media**
   - [ ] EPIC MyChart Patient Portal research study descriptions
   - [ ] Psychology Research Participant Pool (SONA) study descriptions
   - [ ] Scripts for announcements made to groups
   - [x] **Other recruitment document**
   - [ ] No recruitment materials

4. * **If Other was selected above, describe the recruitment document that will be used:**
Participants will be recruited for this study via the CSTP registry (HM20002567) and all recruitment materials are located in that protocol with the exception of the study description that is posted on the CSTP website (cstp.vcu.edu/studies) and Facebook/Instagram/Craigslist.org advertisements that are included as attachments in this protocol. We also provide a social media plan document.

Scripts for communicating with participants (included with this usage protocol) are unique to this study.

5. * **Describe the study procedures/methods for identifying and recruiting participants. Address all of the following three aspects of recruitment in your response.**

1. ***Identification of potentially eligible participants or secondary data/specimens of interest.***
- What database(s) will be queried to identify secondary data/specimens
- How VCU Informatics or VCU IRDS will be used for cohort identification (when applicable, see help text)
- How potential participants' contact information will be obtained

2. ***Recruitment procedures to invite participation in the study (when applicable):***
- How each of the written or verbal recruitment materials and reminders (selected above) will be used
- Who will contact, approach, or respond to potential participants
- Locations where recruitment procedures will take place
- The timing and frequency of recruitment attempts

3. Eligibility screening prior to consent and how those activities will be carried out (when applicable)

See the help text for additional guidance.
Participants will be recruited via the CSTP registry (HM20002567) and other ads that direct potential participants to the CSTP registry.

Potential participants will make the initial contact via telephone by calling the phone number provided on the advertisements, or by going to the website provided on the advertisements. For the initial screening, we will use a multi-study screening process/registry described in HM20002567. Because we use this process for multiple studies, participants are actually screened for all ongoing studies at one time. For this reason, the script is vague. Participants who appear eligible for this usage protocol based on the initial screening questionnaire from the registry are then contacted, told more about this study using a short study description (see attachments), and if interested, participants are invited for an in-person screening, where consent for this study will be obtained.

Participants must complete the screening process described in HM20002567 in order to participate in this usage protocol, and must agree to be part of the CSTP registry in order to participate in this usage protocol (because we do not have study-specific recruitment materials for this study).

Participants who have already consented to participate in the CSTP registry may be contacted via phone or e-mail and told about this study. Individuals who are participants in other, ongoing CSTP studies (participants with whom we have a pre-existing relationship) may be verbally referred to this study and directed to either call the laboratory or visit the website indicated on the advertisements, if they are interested.

Participants who are eligible and who choose to enroll may be contacted via text for appointment reminders if they agree (see scripts).

6. * **Does this study have a separate protocol document (i.e. a multisite or sponsor's protocol) that contains a detailed description of the study's methodology?**

   ○ Yes

   ● **No**

7. * **Since a separate protocol document is not uploaded, describe the proposed research using language understandable to those IRB committee members whose expertise is not scientific. The description must include:**

   1. A statement explaining the study design
   2. A detailed description of all the procedures that will be followed to carry out the study, preferably in sequential order, and in sufficient detail that the study's methods could be replicated
   3. The schedule and frequency of when and how procedures will be conducted (e.g. in person, online, phone, paper, etc.)
   4. A description of all research measures/tests/interventions that will be used, including analyses/tests conducted on specimens/biological samples (if applicable)

   See the help text for additional guidance
   Overview. This study involves 36 cigarette users who will complete 4, within-subject, laboratory sessions that differ by the product used: 1) own brand cigarette, 2) NJOY Ace 2.4% nicotine ECIG (Menthol and Classic Tobacco flavor), 3) NJOY Ace 5.0% nicotine ECIG (Menthol and Classic Tobacco flavor), and 4) NJOY Daily ECIG 6% nicotine (Menthol and Extra Rich Tobacco). The first condition for all subjects will be their own brand cigarette which is completed at the conclusion of the in-person screening session or scheduled immediately following (if the participant is unable to complete this condition at the in-person screening session). The subsequent three sessions will be assigned using a Latin-square following enrollment and within each session participants will sample and evaluate two flavors of each session's product (session flavor order is incorporated into the Latin-square condition order assignment).

   Participants. A total of 36 adults (age 18+) who currently use cigarettes will be enrolled. We will attempt to recruit an equal number of menthol and non-menthol preferring smokers as well as men and women of diverse racial/ethnic backgrounds, although this study is not intended to address gender or race/ethnic differences.

   Recruitment and Enrollment. Participants will first be screened via phone or online, via a multi-study screening process/registry described in HM20002567 (see attachment "Registry consent form and questions"). Participants are automatically screened for all ongoing CSTP studies, but participants can tell study staff if they are interested in screening for a particular study only, and study staff will make a note of this preference.

   Once initial screening is completed (either over the phone or via the internet), potentially eligible participants will be invited to the lab to complete in-person informed consent, additional screening, and familiarization with study procedures (approximately 1 hr, $15/hour compensation). Once participants have been seated in a private study room, research staff will communicate with the participants primarily using Zoom as an intercom, to speak/interact with participants. Prior to in-person data collection, staff will review the informed consent in person and/or using a Powerpoint/video tool to ensure they understand the study, its risks and benefits, and their rights as research participants. Participants will have the opportunity to ask questions to the research staff, prior to signing the consent document. Following documentation of informed consent, participants will complete baseline measures to confirm eligibility, have their blood pressure and heart rate checked, provide a urine sample that will be tested for cotinine level

(to confirm current smoking status) and pregnancy (women only), and provide a exhaled breath carbon monoxide (eCO) sample. Age will be verified by asking participants to provide some form of identification that includes a date of birth. All study procedures (including subjectives, Drug Purchase Task, Cross-Product Drug Purchase Task) will be reviewed/practiced using approved measures and/or Powerpoint/video-based tools. Participants also will complete the Minute Discounting Task.

Individuals whose blood pressure levels are elevated (>=140 mmHg systolic or >=90 mmHg diastolic) during screening or at a session will be provided with a blood pressure information sheet by the research staff (see study document). This sheet will be provided at the first instance of elevated blood pressure observed during the study.

Participants who report illegal drug use at baseline or self-disclose at a later point in the study (other than marijuana/cannabis) will be provided a copy of the Substance Use Resource Handout. Participants are not required to take the handout.

Participants will be asked during the baseline questionnaire whether they would like to receive a brief summary of study findings when the study is completed and if yes preferred contact information (for disbursement of this summary). This information will be completed once the brief study summary is disbursed.

New recruits will replace participants who do not complete the study. Accrual ends when the required number of completers is reached.

Products. Own brand tobacco cigarettes and alternative tobacco products will be purchased locally and/or online by VCU approved staff. If own brand cigarettes are not available at the in-person screening session (due to supply-chain or other access issues), participants will be asked to provide one of their own products and receive compensation for use during that session ($5 for one cigarette). Alternative tobacco products tested will be 1) NJOY Ace 2.4% nicotine ECIG (Menthol and Classic Tobacco flavor), 2) NJOY Ace 5.0% nicotine ECIG (Menthol and Classic Tobacco flavor), and 3) NJOY Daily ECIG 6% nicotine (Menthol and Extra Rich Tobacco).

Of note in terms of regulatory status for the ECIG products tested. Products in Classic Tobacco flavor and Extra Rich Tobacco are currently FDA authorized for marketing/sale in the US (as of 1.24.2023). Products in Menthol flavor are still under FDA review for authorization and have not been denied for marketing/sale and thus are still legal for use for those appropriate age (as of 1.24.2023).

Procedure. Following the in-person screening procedure and confirmation of eligibility, participants will be asked to complete 4 sessions the first of which will begin immediately following the in-person screening (or a day/time that is more convenient for the participant). Subsequent sessions must be scheduled at least 48 hours apart. Participants are not required to abstain from nicotine/tobacco (as we are not testing the ability of these products to suppress abstinence related symptoms or measure acute self-administration behavior), food, or caffeine prior to any session.

Of note, research staff will use Zoom, as an intercom to communicate with participants whenever possible during sessions.

At the start of the session, participants will be asked about symptoms experienced since their last visit (with the exception of session 1, if completed at the in-person screening session; see Presession symptom Checklist). Answers given about respiratory and gastrointestinal symptoms will be compared to the participants' previous answers, and if any symptoms have become more frequent or more severe, the medical monitor and/or study nurse will be asked to review the symptoms. In some cases, we may contact Dr. Lipato to determine if a session can proceed.

Next, participants will have their breath tested (expired carbon monoxide [CO]) and physiologic data collection will begin. We will check blood pressure once at the beginning of the session and again at the end. Heart rate will be measured continuously throughout the session. Immediately after session onset, participants will have a 30-minute rest period.

During rest periods, participants will not be allowed eat or drink outside beverages, but we will provide water to drink and they are invited to use their phone, read books/magazines, or watch movies that we provide to them.

After the 1st rest period, participants will complete subjective measures 1. Immediately after completing subjective measures 1, participants will sample the session-specific product (5 self-directed ECIG/own brand cigarette puffs over 10 minutes). After sampling is complete they will complete subjective measures 2. Ten minutes after their sampling has been completed, they will complete the DPT/CP-DPT. The DPT/CP-DPT takes approximately 10 to 15 minutes to complete. Please note at session 1, only the DPT will be completed, blood pressure will be checked, physio data collection will end, and then the session will end.

In sessions 2 and 3 and 4, after completing the 1st DPT/CP-DPT, participants will start the 2nd 30-minute rest period. After the rest period, participants will complete subjective measures 3. Immediately after subjective measures 3, participants will sample the other session-specific product (5 self-directed ECIG puffs over 10 minutes). After sampling is complete they will complete subjective measures 4. Ten minutes after their sampling has been completed, they will complete the DPT/CP-DPT.

After completing the 2nd DPT/CP-DPT, blood pressure will be checked, physio data collection will end, and participants will be paid for their time.

The study procedures for session 1 should take no more than 70 minutes or 1.2 hours, and for sessions 2 and 3 and 4 should take no more than 140 minutes or 2.3 hours.

Please note there can be some variability in the session times due to participant behavior (i.e., taking shorter/longer than expected to complete measures/tasks).

Session Timeline:

0m – eCO Check; Physiologic data collection begins, additional questions asked.
5m – Begin 30m Rest Period 1
35m – Subjectives 1
40m – Sample Product 1 (puffs)
50m – Subjective 2
60m - 1st DPT/CP-DPT
75m – Begin 30m Rest Period 2 / Physiologic data collection ends; Session 1 end
105m – Subjectives 3
110m – Sample Product 2 (puffs)
120m – Subjective 4
130m – 2nd DPT/CP-DPT
140m – Physiologic data collection ends; Session 2/3/4 end

Note: Product sampling will consist of 5 self-directed sample puffs for own brand cigarettes or ECIG conditions taken over 10 minutes.

Measures.
Baseline measures. During the in-person eligibility screening, we will assess sociodemographic and income-related information, discounting, health and psychiatric conditions, drug and alcohol use, history and patterns of tobacco use, nicotine dependence/craving, and perceived harm and risk of tobacco products using standardized items from national surveys (e.g., Behavioral Risk Factor Surveillance Survey; Tobacco Use Supplement to the Current Population Survey). Urine samples will be tested immediately for cotinine (a major nicotine metabolite) using the NicAlert semi-quantitative test (Jant Pharmaceutical Corporation, Encino, CA), and among women for pregnancy. For eligible/enrolled participants, we will retain a urine sample (≤10 ml) for later analysis of tobacco-related biomarkers. We will also be obtaining baseline physiological measures including: eCO and HR/BP. eCO will be assessed via a BreathCO monitor (Vitalograph, Lenaxa, KS). HR/BP will be measured and saved electronically using software and equipment that sounds an alarm if safety parameters are exceeded (Model 506, Criticare Systems).

The Minute Discounting Task is a series of hypothetical decision scenarios. Each scenario presents a choice between receiving an amount of money now or an amount of money later. These choices are differentiated by the amount of money at each time point and the length of time between the time points. Participants make a choice for five decision scenarios which are automatically adjusted based upon individual responses; while there are approximately 30 potential scenarios, only five are presented to the participant. The task takes less than one minute to complete. Data is collected via Qualtrics survey. Data is stored within Qualtrics under usernames and passwords assigned to some lab staff.

Physiological measures. Physiological measures are being collected primarily for participant safety during sessions. For eligible/enrolled participants, up to 10 ml of urine collected at the in-person screening session will be saved and frozen for later analysis of tobacco-related biomarkers including nicotine and its metabolites (i.e., cotinine), propylene glycol, and (4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol) (NNAL). HR/BP will be measured and saved electronically using software and equipment that sounds an alarm if safety parameters are exceeded (Model 506, Criticare Systems).

Behavioral measures. Our primary behavioral measures are two behavioral choice tasks (Drug Purchase Task; Cross Product-Drug Purchase Task).

The Drug Purchase Task (DPT) assesses hypothetical tobacco product purchasing behaviors for a tobacco product. Please note this measure is tailored to own brand cigarette puffs and ECIG puffs. The outcomes from the DPT include the breakpoint (highest price participants were willing to pay), elasticity (change in amount purchased as price increases), Omax (highest amount individuals paid in any choice, i.e., maximum value of price*quantity), Pmax (the price associated with Omax), and intensity (amount “purchased” when the price is zero/free). Data is collected via REDCap survey and stored under username/password with specific access per user.

The Cross Product (CP)-DPT assesses cross-product purchasing behaviors between various tobacco products offered at a fixed amount and own brand cigarettes offered at varying prices ($0-20.48). Please note this measure is tailored to ECIG puffs. The main outcome for the CP-DPT is cross-price elasticity, or the extent to which purchasing of the session-specific product increases when the price of own brand cigarettes increase. Both the DPT and CP-DPT tasks are programmed to end early if participants report zero consumption for assessed products. Estimated time per measure is <3 min. Data is collected via REDCap survey and stored under username/password with specific access per user.

Subjective measures. Repeatedly within each condition we will use the Adapted Hughes/Hatsukami Questionnaire, the Direct Effects of Nicotine Scale, the Direct Effects of Tobacco Scale, Pennington VAS Scale and several items that utilize the Generalized Labeled Magnitude Scale and the General Labeled Hedonic Scale to measure tobacco abstinence symptoms and other effects before and after each product sampling.

Subjectives 1 and 3 will not include product-specific questions (Direct Effects of Tobacco Scale, Generalized Labeled Magnitude Scale and the General Labeled Hedonic Scale).
Subjectives 2 and 4, will include product-specific questions.

We will also ask a validation question during Subjectives 2 and 4 related to flavor of the product that was tried.

All data is collected via REDCap or Qualtrics survey and stored under username/password with specific access per user.

Tobacco Cessation Resources. A brief handout containing information about tobacco cessation and available resources will be provided to all participants who consent to this study. Participants are not required to take the handout. This handout will be given at the end of their study participation (at screening if ineligible, at the end of their last study session, or via email if they self-withdraw or are withdrawn by the PI/medical monitor). We provide this information as it may assist individuals who are considering quitting tobacco now and/or quitting tobacco in the future.

Data analysis. Subjective, physiological, and behavioral data will be prepared as reported elsewhere (e.g., Barnes et al., 2017; Rusted et al., 1998; Cobb et al., 2010). Elasticity is estimated using an exponential demand function with nonsystematic DTP data excluded based on two criteria: trend, or whether the participant had a general decrease in consumption from the lowest to highest price; and bounce, or whether a participant reported higher consumption at sequential higher prices (Stein et al., 2015). In general, analysis will involve a mixed (between- and within-subject) ANOVA. Demographic data will be examined to determine if there are significant between-group differences on measures that may be related to study outcomes. Unexpected between group differences will be considered as potential covariates in the primary analysis (see Evans et al., 2006). Statistical analyses may utilize regression, ANOVA, or mixed linear models. Adjustments for sphericity violations and post-hoc testing using Tukey's HSD or planned contrasts with Bonferroni corrections will be used (Keppel, 1991). Based upon the type and amount of missing data, we may use accepted techniques such as multiple imputation (Allison, 2001).

8. * **The IRB only reviews research activities, so indicate for each of the study activities described in the question above or in the protocol which activities are:**

   - Being performed exclusively for research purposes (i.e. they would not otherwise be done apart from this study) VERSUS.
   - Alterations of routine activities/procedures (e.g. the study is altering the timing, frequency, method, location, amount, etc.) VERSUS.
   - Being done for other purposes and whose data/results will be used secondarily in the study (e.g. standard medical or psychological tests, routine education practices, quality improvement initiatives, etc.).
   See the help text for additional guidance

   All of the procedures described above are performed exclusively for research purposes. There are no alterations of routine procedure and no procedures would be performed if these individuals were not taking part in this research study.

9. **If applicable, describe alternatives (research or non-research) that are available to potential participants if they choose not to participate in this study:**
   N/A

10. **Upload any supporting tables or documents (e.g. protocol documents, figures/tables, data collection forms, study communications/reminders):**

    Upload ALL instruments/guides that will be used or that participants will experience (i.e. see, hear, complete), including measures, scripts/questions to guide interviews, surveys, questionnaires, observational guides, etc,:

    Upload ALL recruitment and screening materials, including such as ads, flyers, telephone or in-person scripts, letters, email invitations, TelegRAM announcements, and postcard reminders, screening scripts, screening forms, and screening measures:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Informed Consent	P3 TASTE_Informed Consent_CLEAN_1.29.2024.pdf	0.15	2/20/2024 10:22 AM	Rabia Imran	Consent/Assent/Information Sheet	Yes
View	Consent - Tool	P3TASTE_Consent_Presentation_1.29.2024.pptx	0.06	1/30/2024 1:34 PM	Rabia Imran	Consent/Assent/Information Sheet	Yes
View	Social Media Plan	P3-TASTE Social Media Plan_10.2.2023.docx	0.01	10/2/2023 3:29 PM	Caroline Cobb Amey	Recruitment/Advertising	Yes
View	Social Media and Craigslist Ads	P3-TASTE_facebook and craiglist ads_10.2.2023.docx	0.01	10/2/2023 3:29 PM	Caroline Cobb Amey	Recruitment/Advertising	Yes
View	Substance Use Resources Handout	CSTP Substance Use Resources_8.11.2023.docx	0.01	8/11/2023 5:11 PM	Caroline Cobb Amey	Other	Yes
View	Subjective Measures	P3-TASTE-Session Subjective Measures_CLEAN_08.09.2023.doc	0.03	8/11/2023 5:10 PM	Rabia Imran	Research Measure	Yes
View	P3 TASTE Advertisement for CSTP Website	P3 TASTE - CSTP Website Study Description_CLEAN_08.08.2023.docx	0.05	8/11/2023 5:09 PM	Rabia Imran	Recruitment/Advertising	Yes
View	Presession Symptom Questions	P3-Presession symptom Checklist-CLEAN_08.09.2023.docx	0.05	8/11/2023 5:08 PM	Rabia Imran	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Baseline Self Report Physio Measures	P3-TASTE_Baseline forms All_CLEAN_8.11.2023.docx	0.06	8/11/2023 5:07 PM	Rabia Imran	Research Measure	Yes
View	Text, Email, Call Scripts	P3-TASTE_Phone_e-mail_text scripts_08.09.2023_CLEAN.docx	0.10	8/11/2023 5:06 PM	Rabia Imran	Study reminders/communications	Yes
View	Referral Program Card Template	P3_Referral program card_06.02.2023_CLEAN.docx	0.03	6/13/2023 1:48 PM	Rabia Imran	Recruitment/Advertising	Yes
View	COVID-19 Questions	COVID_Questions_P3_no longer using.docx	0.02	6/13/2023 1:35 PM	Rabia Imran	Other	Yes
View	P3 Taste_ETM	P3-TASTE_Measures_ETM__no longer using.docx	0.04	6/13/2023 1:35 PM	Rabia Imran	Research Measure	Yes
View	Tobacco Cessation Resources Handout	Cessation_handout_RI_04.29.2021.pdf	0.01	2/1/2023 3:32 PM	Caroline Cobb Amey	Other	Yes
View	U54 Grant Application Without Budget	U54 Grant Application BUDGET PAGES DELETED FOR IRB.pdf	0.01	10/28/2022 2:17 PM	Rabia Imran	Funding Proposal	Not Applicable
View	CP-DPT & DPT	P3-TASTE Drug Purchase Tasks_9.2.2022.docx	0.01	10/28/2022 2:03 PM	Rabia Imran	Research Measure	Yes
View	CP-DPT & DPT - Tool	DPT_CDPT presentation_10.28.2022.pptx	0.01	10/28/2022 2:03 PM	Rabia Imran	Research Measure	Yes
View	Subjective Measures - Tool	Subjective Measures presentation_10.28.2022.pptx	0.01	10/28/2022 2:00 PM	Rabia Imran	Research Measure	Yes
View	Barnes Biosketch	P3 Barnes biosketch 06.22.17.FINAL.docx	0.01	10/28/2022 1:55 PM	Rabia Imran	CV/Biosketch	Not Applicable
View	Lipato Biosketch	Lipato Biosketch.pdf	0.01	10/28/2022 1:54 PM	Rabia Imran	CV/Biosketch	Yes
View	Caroline Cobb (Amey) CV	CV_Cobb_August 2022.docx	0.01	10/28/2022 1:54 PM	Rabia Imran	CV/Biosketch	Yes
View	Baseline Discounting Task - MDT	P3_TASTE_Discounting Task_11.7.2018.pdf	0.01	10/28/2022 1:54 PM	Rabia Imran	Research Measure	Yes
View	U54 Project 3 Grant Docs	U54_Project 3 only docs.pdf	0.01	10/28/2022 1:53 PM	Rabia Imran	Funding Proposal	Not Applicable
View	CSTP Parking Map	CSTP Parking Map.docx	0.01	10/28/2022 1:52 PM	Rabia Imran	Other	Not Applicable
View	Criticare HR/BP Manual	Criticare_Vitalcare_506N3_-_Service_manual.pdf	0.01	10/28/2022 1:52 PM	Rabia Imran	Other	Not Applicable
View	Expired Air CO Manual	CO Monitor Manual.pdf	0.01	10/28/2022 1:51 PM	Rabia Imran	Other	Not Applicable
View	Information about Blood Pressure	BP results P3 flux 8.22.2022.docx	0.01	10/28/2022 1:51 PM	Rabia Imran	Study reminders/communications	Yes
View	CSTP Registry Consent and Survey	CSTP Registry Consent Form and Questions.pdf	0.01	10/19/2022 3:27 PM	Caroline Cobb Amey	Other	Not Applicable

Project Details

An intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

An interaction includes communication or interpersonal contact between investigator and subject. It may include in-person, online, written, or verbal communications.

Secondary information/biospecimens are information or biospecimens that have been or will be collected for some other "primary" or "initial" activity and that will be used secondarily in the research study.

1. * **Select all of the following types of interventions that apply to this study (selections will branch):**
   - [x] **Social/Behavioral interventions or experimentation / Tasks / Environmental manipulations**
   - [ ] Deception (misleading participants through false or incomplete information)
   - [x] **Drug(s) / Biologics / Supplement(s) / Other Compounds (investigational products or products whose administration is dictated by the study protocol and not per the physician's clinical judgment)**
   - [ ] IV contrast administration for research-related imaging (will branch to the Drugs page)
   - [ ] Placebos
   - [ ] Safety and/or effectiveness evaluation of Bio-Medical Device(s), including in-vitro diagnostic devices/assays, mobile medical apps, software functions, and HUDs used in clinical investigations
   - [ ] Washout Periods
   - [ ] Expanded Access – Treatment Use of an Investigational Product
   - [x] **Medical or Surgical Procedures (eg: physical exam, clinical procedures, scans, etc)**
   - [x] **Specimen/biological sample collection**
   - [ ] None of the Above

2. * **Select all of the following types of interactions and methods of data collection that apply to this study (selections will branch):**
   - [x] **Surveys / Questionnaires /Written responses to questions (including data entry)**
   - [x] **Active Internet data collection (i.e. using the internet to collect data, including online surveys, data collection via Zoom, apps, etc.)**
   - [ ] Passive Internet data collection (i.e. passively observing online behavior, bots)
   - [ ] Interviews / Focus Groups / Verbal responses to questions
   - [x] **Audio / Video recording or photographing participants**
   - [ ] Observations
   - [ ] Educational Settings/Assessments/Procedures
   - [ ] None of the Above

3. * **Select all types of recordings that will be made:**
   - [x] **Audio**
   - [x] **Video**
   - [ ] Photographs

4. * **Describe the purpose of the recordings, who will be recorded and when such recordings will occur:**
   We will be using Zoom as an intercom for communications with participants during in-person screening and study sessions. Sometimes, such as when explaining procedures or answering questions, research staff may notify participants and then switch the camera on the participant computer 'on' so that we can facilitate a face to face conversation. Other times, all cameras may be off and/or research staff may have only their computer camera 'on' so that participants can see the researcher.

Zoom will not be recorded or stored or linked to participant IDs or used for any analysis purpose other than facilitating face to face communications in combination with social distancing.

5. * **Select all types of secondary information and/or specimens that apply to this study (selections will branch):**
See the help text for definitions.

- [x] **Individually Identifiable Health Information (PHI)**
- [ ] Secondary data/specimens NOT from a research registry or repository
- [x] **Information/specimens from a research registry or repository (Usage Protocol)**
- [x] **Information/specimens originally collected for a previous research study**
- [ ] Publicly available information/specimens
- [ ] Government-generated or collected information that was or will be obtained for nonresearch activities [only applicable to research conducted by or on behalf of a Federal department or agency]
- [ ] No secondary data/specimens will be used

Behavioral Intervention/Task Details

This page asks for details about the social/behavioral intervention, task, or environmental manipulation in the research.

Interventions include both physical procedures by which information is gathered and manipulations of the subject or the subject's environment that are performed for research purposes. This might include activities such as playing computer games, performing a task, thought/cognition activities, environmental manipulations, and educational activities.

If the study only involves surveys, interviews, or secondary data collection, go back to the Project Details page and uncheck "Social/Behavioral interventions or experimentation / Tasks / Environmental manipulations" in Question 1.

1. * **Describe the duration of the social/behavioral intervention, task, or environmental manipulation:**
   4 sessions each from 1.2 to 2.3 hours

2. * **Describe any potential harms or discomforts that participants could experience during the intervention activity:**
   Physical Risks:
   1. You may experience mild frustration while completing some of the study-related tasks.
   2. On very rare occasions, you may experience small droplets of liquid during inhalation of the e-cigarette we provide. You may find these droplets to be unexpected and/or unpleasant. This experience has been reported by e-cigarette users, and they report that it is an annoyance that does not appear to present any known medical danger. If this occurs, we will immediately replace the e-cigarette device you are using.
   3. The e-cigarette liquid that we give you may contain less or more nicotine than you are used to, although some e-cigarette users report using these products. Inform the study staff immediately if you experience any discomfort. You may also experience side effects from products that contain nicotine such as acute increases in heart rate and blood pressure, sweating, lightheadedness, dizziness, nausea, and nervousness. These side effects are unlikely in individuals who use cigarettes regularly.
   4. The Centers for Disease Control and Prevention advises that e-cigarette, or vaping products are unsafe for youths, young adults, or women who are pregnant. Adults who do not currently use tobacco products should not start using e-cigarette, or vaping, products. If you use e-cigarette products, monitor yourself for the below symptoms and promptly seek medical attention if you have concerns about your health.
   a. Some people who use e-cigarettes have reported experiencing seizures. Some of these individuals reported a prior history of seizures or using other substances at the same time as their e-cigarette.
   b. In some cases, e-cigarette use has led to respiratory illnesses such as difficulties breathing, shortness of breath, cough, and/or chest pain before hospitalization. In some cases, e-cigarette use has led to death, although most of these cases have been related to vaping THC.
   c. In some cases, e-cigarette use has been associated with symptoms of mild to moderate gastrointestinal illness such as nausea, abdominal pain, vomiting, diarrhea, fevers, or fatigue.
   5. The use of e-cigarettes may include other side effects/risks such as a sore or scratchy throat and headache.
   6. The researchers will let you know about any significant new findings (such as additional risks or discomforts) that may make you change your mind about participating in the study.

   Non-physical Risks
   1. Participation in research might involve some loss of privacy. There is a small risk that someone outside the study could see and misuse information about you.
   2. The study questionnaires ask personal questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable.

3. * **Will the intervention activity be physically invasive or painful?**
   - ○ Yes
   - ● **No**

4. * **Describe the impact the intervention activity will have on participants, including the nature and duration of any impact(s):**
   Participants will be using an ECIG/cigarette that contains nicotine. They may experience the effects of nicotine use which could include acute increases in heart rate and blood pressure, sweating, lightheadedness, dizziness, nausea, and nervousness, although these are less likely in individuals who use nicotine-containing products regularly. All of the participants are experienced, cigarette smokers. The duration of these impacts is expected to be no longer than the length of the session.

5. * **In the investigator's opinion, is there any reason to think that the participants will find the intervention activity offensive or embarrassing? Explain why or why not.**
   No.

Bio-Medical Drug / Biologic / Supplement / Other Compound Details

1. * **List all drugs and/or biologics:**

	Drug	Manufacturer	Types	FDA Labeling	IND Holder	IND Number
View	NJOY Ace 2.4% nicotine - Menthol (flavor)	NJOY LLC	Other (Drug or Compound Not Listed Above)	Not Applicable	Not Required	
View	Own brand cigarettes	Various Manufacturers	Other (Drug or Compound Not Listed Above)	Not Applicable	Not Required	
View	NJOY Ace 2.4% nicotine - Classic Tobacco (flavor)	NJOY LLC	FDA Approved and being used as approved	Not Applicable	Not Required	
View	NJOY Ace 5.0% nicotine - Menthol (flavor)	NJOY LLC	Other (Drug or Compound Not Listed Above)	Not Applicable	Not Required	
View	NJOY Ace 5.0% nicotine - Classic Tobacco (flavor)	NJOY LLC	FDA Approved and being used as approved	Not Applicable	Not Required	
View	NJOY Daily 6% nicotine - Menthol (flavor)	NJOY LLC	Other (Drug or Compound Not Listed Above)	Not Applicable	Not Required	
View	NJOY Daily 6% nicotine - Extra Rich Tobacco (flavor)	NJOY LLC	FDA Approved and being used as approved	Not Applicable	Not Required	

2. * **Will the Investigational Drug Service (IDS) pharmacy be utilized:**
Not Applicable

3. * A. For each drug/biologic listed above**, upload an investigator's drug brochure or package insert/FDA labeling.**

B1. <u>For drug products that require an IND</u>, upload at least one of the following for verification of the IND number:
- External sponsor's protocol including IND number <u>and</u> signed Form FDA 1572 for the VCU Principal Investigator
- Communication from the external sponsor verifying the IND number <u>and</u> signed Form FDA 1572 for the VCU Principal Investigator
- VCU sponsor-investigator's FDA IND protocol including IND number
- Communication from the FDA with verification of the IND number

B2. *For drug products that qualify for IND exemption* under under 21 CFR 312.2(b), upload one of the following for each applicable drug:
- A document explaining, with protocol-specific information, how the drug's use in this study meets the relevant criteria for IND exemption under 21 CFR 312.2(b).
- The completed "Determination of IND Exemption for Marketed Drugs" form available on the VCU Faculty-Held IND or IDE website at go.vcu.edu/indide.
- External sponsor's protocol including IND exemption information
- Communication from the external sponsor verifying the IND exemption
- Communication from the FDA with verification of IND exemption

C. <u>If the Investigational Drug Service Pharmacy (IDSP) is not utilized</u>, upload the IDSP management plan approval.

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Informed Consent	P3 TASTE_Informed Consent_CLEAN_1.29.2024.pdf	0.15	2/20/2024 10:22 AM	Rabia Imran	Consent/Assent/Information Sheet	Yes
View	Consent - Tool	P3TASTE_Consent_Presentation_1.29.2024.pptx	0.06	1/30/2024 1:34 PM	Rabia Imran	Consent/Assent/Information Sheet	Yes
View	Social Media Plan	P3-TASTE Social Media Plan_10.2.2023.docx	0.01	10/2/2023 3:29 PM	Caroline Cobb Amey	Recruitment/Advertising	Yes
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Sample Collection Details

1. * **Select all of the types of samples that will be collected as part of this study.**
   - [ ] Amniotic Fluid
   - [ ] Blood
   - [ ] Buccal Smears
   - [ ] Saliva
   - [ ] Tissue
   - [x] **Urine**
   - [ ] Stool
   - [x] **Other**

2. * **If Other, please describe the type of sample being collected:**
   At screening and upon arrival at the laboratory for the research sessions, participants' expired air carbon monoxide will be measured. Samples will not be stored.

3. * **In order to collect urine, will an indwelling catheter be placed solely for the research study:**
   - ○ Yes
   - ● **No**

4. * **Describe how the sample will be collected and the collection schedule. For each type of sample, include information about**

   - The procedures that will be followed to collect the sample
   - The role(s) of the individuals who will collect the sample
   - The volume/size range of the sample
   - The timing and frequency of sample collection

   Expired air carbon monoxide samples will be taken using the device manufacturer guidance for length of breath hold and timing at screening and at the beginning of each session. Disposable mouthpiece tubes will be used at each participant/session. Carbon monoxide device readings will be recorded by research staff following each test.

   Urine will be collected during the baseline screening to test for recent nicotine exposure and for current pregnancy for women. About 10 to 30 mL is required for testing purposes, participants may provide more but it is not required.

   For eligible/enrolled participants, up to 10 ml of urine collected at the in-person screening session will be saved and frozen for later analysis of tobacco-related biomarkers including nicotine and its metabolites (i.e., cotinine), propylene glycol, and (4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol) (NNAL).

   Participants will be given a urine collection cup to collect their own urine in a nearby bathroom and return to the laboratory space (<20 ft away) where the specimen will be processed. After screening tests have been completed and samples stored, the urine sample is disposed using approved procedures for biohazardous waste.

   Research staff will be responsible for performing all sample collection procedures.

5. * **Will genetic testing or genetic analyses be conducted on any of the samples:**
   - ○ Yes
   - ● **No**

Active Internet Data Collection

1. * **Describe the platform/technology chosen for collecting the data and transmitting data securely over the internet. If proposing a non-VCU approved platform, give the rationale for selecting the technology instead of a VCU-approved platform.**
   The in-person screening questionnaires, questionnaires administered during session, and the follow-up survey will be administered via REDCap. All of the data will be stored in REDCap and viewing will be restricted to those personnel associated with this protocol (listed under personnel).

   There are several reasons for choosing REDCap. First, electronic administration of forms is more efficient than paper forms and leads to less data entry (and possible errors). Second, REDCap is a secure way to collect data from participants.

   One measure (Minute Discounting Task) is collected via a VCU-supported Qualtrics account.

2. * **Describe how data will be linked or unlinked to identifiers including email addresses, names, and/or IP address.**
   If a participant enrolls in this study, they are given a numeric code (the study ID) that is connected 1) to their consent (i.e., name) via a paper key, and 2) added to their CSTP registry information (the registry ID) via a separate variable in our administrative form.

   The study ID appears on all subsequent documents/data forms.

   The paper key is maintained in the study binder so that we can demonstrate that a particular data set is associated with a particular consent document. This paper key and consent documents are stored separately from each other and separately from all data (under double lock).

   The electronic key is maintained in the registry project and the study project.This key will be deleted when data collection for the study has been completed.

3. * **How will you protect your data collection from fraudulent responses:**
   As data will be collected in-person, with a small number of participants, we do not anticipate issues with fraudulent responses (i.e., that might occur if we were using a completely online survey).

4. * **Is there an alternative method for completion of the data collection other than the internet?**
   - (●) **Yes**
   - ( ) No

5. * **If yes, describe the alternative(s).**
   Study forms/measures can be completed on paper if necessary during in-person assessments.

6. * **Describe how individuals will be able to skip or not answer particular questions. If any questions are mandatory, provide justification.**
   Participants do not have to answer any particular question that they do not want to answer. If a participant does not want to answer a question, they can inform study staff who can note this and remove answers (some of our questionnaires do not have an option to skip the question because it is difficult to add this option in REDCap without making the forms confusing, and also, if we make all the questions in REDCap optional, we find that this leads to participants missing questions by mistake).

7. **If not including children, describe any procedures used to verify that research participants are adults.**
   We ask participants for their age and date of birth several times (telephone or online screening, in-person screening) and verify that the answers are the same. We will also check ID during the in-person screening to verify that the participant is eligible.

Secondary Data/Specimen Details

1. * **Describe the source(s) and nature of the information/specimens being obtained. This response should:**

   a. Identify where the data/specimens will come from (e.g., another researcher's registry, pathology lab, commercial source, medical records, etc.); and
   b. List what types of specimens will be obtained (when applicable); and/or
   c. List all data elements that will be obtained (when applicable). A data collection form or other documentation may be uploaded and referenced here.
   Contact information and eligibility requirements are obtained from this registry. Eligibility questions include information about cigarette and electronic cigarette use, alcohol, and drug use, health issues, and medication use. This data is used for screening and eligibility purposes.

   We may also ask participants who are currently participating in other, ongoing studies at the CSTP if they are interested in participating in this study. There is a script for this communication in the documents section. Interested participants will be asked to complete the in-person screening visit for this study.

2. * **Describe whether any agreement exists between you and data/specimen provider that states you will never have access to the ability to identify the participants (i.e. access to identifiers or the code key) and that you will not attempt to re-identify individuals.**
   The registry contains identifying information such as names. If a participant enrolls in this study, they are given an alpha-numeric code. We do plan to link this alpha-numeric code with participants' registry data (as a separate variable that we use administratively to keep track of which registry participants are in which usage protocol). This separate variable can be deleted when this usage protocol is closed. We can re-identify participants.

3. * **When the information/specimens were originally collected, did individuals provide consent for secondary research use of their data/specimens (i.e. consent to another research study or to a research registry)?**
   - (●) **Yes**
   - ( ) No

4. * **Provide name(s) of the registry/repository being accessed.**
   CSTP Overall Screening and Registry

5. * **Site having responsibility for the management of this registry/repository:**
   - (●) **VCU**
   - ( ) Non-VCU

6. **If the registry / repository is located at VCU, provide the IRB number for the registry / repository.**
   HM20002567

7. * **Is the original consent form that participants signed upon entry into the registry /repository available?**
   - (●) **Yes**
   - ( ) No

8. **If YES, the original consent is available, upload it for the IRB to reference**

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Costs to Participants

1. * **Select all categories of costs that participants or their insurance companies will be responsible for:**

- [x] **Participants will have no costs associated with this study**
- [ ] Study related procedures that would be done under standard of care
- [ ] Study related procedures not associated with standard of care
- [ ] Administration of drugs / devices
- [ ] Study drugs or devices
- [ ] Other

Compensation

It is recommended that investigators consult with VCU Procurement Services before proposing a compensation plan (monetary or non-monetary) to the IRB to ensure the plan will comply with VCU policies. Refer to WPP XVII-2 for the IRB's guidelines about compensating research participants.

1. * **Describe any compensation that will be provided including:**
   1. total monetary amount
   2. type (e.g., gift card, research pre-paid card, cash, check, merchandise, drawing, extra class credit)
   3. how it will be disbursed
   4. how you arrived at this amount
   5. What identifiers and tax forms will be required for compensation purposes (i.e. W-9 form, SSN, V#, addresses, etc.)

   1. Participants will be paid $15/hr for completing the in-person screening to determine eligibility to participate (~1.5 hrs; ~$23). For the study sessions, participants will be paid $50 for completion of the first session (+$5 if they provide one own brand cigarette for use; $55 in total), $75 for session 2, $100 for session 3, and $125 for session 4.

   For the in-person screening/sessions, participants will be provided $12 for travel/parking compensation.

   Total potential compensation for this study is up to $438.

   This amount does not include potential referral card fee payments (up to an additional $100).

   Participants who complete the in-person screening visit will be given 5 cards with information about our laboratory and a numerical/alphabetical code that is linked to that participant (name, e-mail address). These cards could be given to friends/family members who might want to participate in any of the lab's studies which include an in-person screening visit. If a friend/family member with a card appears eligible to participate (via the CSTP registry), comes to an in-person screening visit, and brings the card (for any of our studies that include an in-person screening visit), we will send the original participant $20 per card via Amazon gift code to their e-mail address. The original participant will not be told who brought in the card(s). In total, the maximum amount a participant could receive from this referral program is $100. Because of the relatively low amount of money participants can earn from this referral program, as well as the low likelihood that all five cards linked to one participant will be brought back to the laboratory, we do not feel this strategy is coercive.

   2. All payments will be in the form of cash with the exception of the referral card fee payments (Amazon gift card via email).

   3. Payments are dispersed by the research staff in-person or via email.

   4. Payment amounts were derived from previously performed studies at this lab and other groups with similar activities/participant populations.

   5. Participants will be asked to complete a W-9 tax form with all fields completed including SSN for any in-person cash payments (although they can refuse to complete this form).

2. **If compensation will be pro-rated, explain the payment schedule.**
   If a session must be discontinued for reasons beyond the control of the participant, the participant will be paid for the time spent the time spent in the laboratory ($15/hour).

   Regarding the referral fee program - Participants receive $20 per card returned via Amazon gift code to their e-mail address. In total, the maximum a participant could receive from this referral program is $100.

Contingency Plan

This page will be used by the IRB in the event that an institution-wide emergency situation arises that requires contingency plans.

A contingency plan describes the alternative procedures that a study would want to use in case of an emergency that prevented normal study activities from occurring. It is a form of adaptive protocol. It enables the VCU IRB to quickly approve alternative study activities along with criteria for when those activities would or would not be put into effect. For example, in 2020, some studies had a COVID-19 Contingency Protocol approved that described alternative remote procedures that they would switch to whenever the University restricted in-person research activities.

In all studies, investigators are strongly encouraged to plan prospectively and build flexibilities into their regular protocols (regardless of whether an emergency situation exists) as well as think about what they would do in an emergency situation. For example, windows for timed study visits, ranges instead of exact values, flexibilities in inclusion criteria, etc. Flexibility and adaptations that are built into the protocol will reduce the number of changes that have to be submitted to the IRB and should reduce the number of incidents of deviations and noncompliance by investigators.

Further instructions and smartform questions on this page will be released from the IRB in the event of such an institution-wide emergency situation.

Research Complete

Protocol Progress:
● **INITIAL SETUP**
● **BACKGROUND, RATIONALE & GOALS**
● **RESEARCH PLAN**
④ CONSENT PLAN
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Consent Process

1. * **List all consent groups:**

	Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
View	All participants	Signed Consent by Participant	No Waivers Requested	Research Nurse Principal Investigator Co/Sub-Investigator Research Coordinator Research Assistant Trainee/Student(working on project)		Not using electronic signature platforms	Consent will be obtained in a private room located at the Center for the Study of Tobacco Products (CSTP). Consent will be obtained at in-person screening. Consent will be on-going and assumed when a participant makes and completes follow up appointments. Participants are read the consent form aloud via a pre-recorded voice-over Powerpoint presentation/video or in real-time by a staff member and encouraged to ask questions before signing. At any point participants can chose not to continue with the various levels of screening for this study (the online/telephone consent/screening and in-person consent/screening).	Removing physical symbols of authority like white coats or police badges Sitting down beside the participant instead of standing over them Other protection(s) not listed here – describe below	Participants will be given as much time as necessary to consider the research study and consent form before deciding whether or not to participate.	

2. **Upload any consent / assent documents:**

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View	Criticare HR/BP Manual	Criticare_Vitalcare_506N3_-_Service_manual.pdf	0.01	10/28/2022 1:52 PM	Rabia Imran	Other	Not Applicable
View	Expired Air CO Manual	CO Monitor Manual.pdf	0.01	10/28/2022 1:51 PM	Rabia Imran	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Information about Blood Pressure	BP results P3 flux 8.22.2022.docx	0.01	10/28/2022 1:51 PM	Rabia Imran	Study reminders/communications	Yes
View	CSTP Registry Consent and Survey	CSTP Registry Consent Form and Questions.pdf	0.01	10/19/2022 3:27 PM	Caroline Cobb Amey	Other	Not Applicable

Consent Plan Complete

Protocol Progress:
● **INITIAL SETUP**
● **BACKGROUND, RATIONALE & GOALS**
● **RESEARCH PLAN**
● **CONSENT PLAN**
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Risks, Discomforts, Potential Harms and Monitoring

1. * **Describe the risks of each research procedure to participants or others. For each identified risk, provide an assessment of the anticipated seriousness and likelihood of the risk. Some examples of possible risks include but are not limited to:**

   - **Physical risks (e.g. bodily harms or discomforts, side effects, etc.)**
   - **Psychological risks (e.g. emotional, mental, or spiritual harms or discomforts, changes to thoughts, beliefs, or behaviors, etc.)**
   - **Research data risks (e.g. loss of confidentiality and privacy)**
   - **Social or legal risks (e.g. impacts on relationships or reputation, legal or criminal justice actions for self or others, etc.)**
   - **Financial risks (e.g. impacts on income, employability, or insurability, loss of services, etc.)**
   - **Other risks (e.g. unforeseeable risks of experimental procedures, risks related to particular study designs (randomization, washout, placebo, withholding care/services, deception), etc.)**

   See the help text for additional guidance.

   There are few risks associated with this study.

   1. There is some risk of frustration while completing study procedures.

   2. We have read that users of the ECIG device we are using in this study sometimes experience small drops of liquid during inhalation, and we have occasionally noticed this during our testing of the product. If this occurs, participants may find the droplets unexpected and/or unpleasant. We believe that is unlikely that these small droplets of liquid present any medical danger.

   3. The ECIG liquid used may contain less or more nicotine than participants normally ingest, but these effects are unlikely in individuals who use cigarettes regularly. Participants also might experience side effects from products that contain nicotine such as acute increases in heart rate and blood pressure, sweating, lightheadedness, dizziness, nausea, and nervousness.

   4. The Centers for Disease Control and Prevention advises that e-cigarette, or vaping products are unsafe for youths, young adults, or women who are pregnant. Adults who do not currently use tobacco products should not start using e-cigarette, or vaping, products. If you use e-cigarette products, monitor yourself for all of these symptoms and promptly seek medical attention if you have concerns about your health.
   a. Some people who use e-cigarettes have reported experiencing seizures. Some of these individuals reported a prior history of seizures or using other substances at the same time as their e-cigarette.
   b. In some cases, e-cigarette use has led to respiratory illnesses such as difficulties breathing, shortness of breath, cough, and/or chest pain before hospitalization. In some cases, e-cigarette use has led to death, although most of these cases have been related to vaping THC.
   c. In some cases, symptoms of mild to moderate gastrointestinal illness such as nausea, abdominal pain, vomiting, diarrhea, or fevers or fatigue have been reported.

   5. The use of e-cigarettes may include other side effects/risks such as a sore or scratchy throat and headache.

   6. There is some risk of loss of confidentiality.

   7. The procedures in this research are known to hurt a pregnancy or fetus in the following ways: cigarette smoking during pregnancy raises risk for pre-term birth, birth defects, and bleeding during pregnancy/delivery; cigarette smoking also can negatively impact fertility. The research may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. Participants should not be or become pregnant or father a baby while on this research study.

   8. In addition to these risks, this research may hurt participants in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

2. * **Describe how each of the risks/harms/discomforts identified above will be minimized:**
   During the sessions, if the participant reports experiencing small droplets of ECIG liquid during inhalation, we will immediately replace the product they are using in the session.

   We will inform participants of the other ECIG-related side effects during the informed consent process. These risks are minimized by limited exposure to ECIGs in study sessions. We do not anticipate participants taking more than 5-10 total puffs per session. The risk of overexposure to nicotine from the ECIGs administered is also minimized by enrolling

current cigarette smokers (cigarettes are among the most efficient and effective nicotine delivery systems currently marketed).

The risk of seizures is minimized by excluding participants with any history of seizures, and by having a full-time RN available, as well as monitoring of vital signs. In addition, some of the reported seizures occurred in users who were using other substances such as marijuana or amphetamines--the risk of seizures in this study is reduced as we are administering nicotine and no other substances.

The risk of respiratory illnesses related to ECIG use is minimized by the limited ECIG use that occurs in each session. Participants are expected to take no more than 5-10 puffs of either their own brand CIG or session-specific ECIGs at each session. Participants are informed about recent reports of ECIG-related respiratory illnesses and are informed that the CDC has advised people to stop vaping. Participants are also advised to monitor themselves for symptoms and to seek medical attention if they have concerns. In addition, we will ask about respiratory and gastrointestinal symptoms at screening and before each session begins. Answers given at the beginning of each session will be compared to the participants' previous answers, and if any symptoms have increased, Dr. Lipato will be asked to review the symptoms. In some cases, we may contact Dr. Lipato to determine if a session can proceed.

We recruit individuals aged 18 + who use nicotine-containing products at similar or higher daily/weekly frequencies that they would be exposed in the laboratory setting. Our protocol ensures that study-related nicotine/tobacco exposure is similar to or less than what participants may expose themselves to as part of their ordinary life.

Nicotine-related side effects: It is possible that participants may experience unpleasant symptoms associated with over consumption of nicotine during study sessions when tobacco products are administered (e.g., increased heart rate/blood pressure, dizziness, nausea). Importantly, this population will have experience with nicotine consumption. We will exclude individuals at baseline screening that have high blood pressure (meet safety criteria defined below) or withdraw those enrolled if we observe repeated high blood pressure during study sessions (dependent on consultation with medical monitor). The likelihood of these effects is very low. As part of the informed consent process, we will inform participants of potential side effects associated with nicotine consumption.

Our sessions and surveys are optimized in length to make them as short as possible while ensuring collection of primary study outcomes. We believe sessions that last <2 hours and the number of subjective and behavioral assessments per session are not worthy of noting as discomforting.

Loss of confidentiality is a possibility but we minimize this risk by using a double locked filing cabinet, a password protected database (REDCap) and limiting access to authorized study personnel only. We also assign a unique ID code to participants instead of using their name or other identifiable data to track their participation.

The support of the research staff will minimize potential frustration during study sessions. Research staff will be available for questions and support throughout the study sessions. If ever study tasks become unmanageable, participants will be offered the opportunity to end the session early and potentially repeat the session at a later date or to discontinue participation. The study staff is well trained to identify signs of frustration and proper support responses.
.

In addition, non-invasive computerized monitoring equipment allows for minute-by-minute, real-time monitoring of participants' heart rate. If needed, we can monitor blood pressure as well throughout the session. Research personnel are trained to alert the research nurse if heart rate continually exceeds 120 beats per minutes, if systolic BP continually exceeds 160 mm Hg, or if diastolic BP continually exceeds 100 mm Hg. Individuals whose heart rate and/or BP levels remain elevated will be monitored by the nurse, and if necessary emergency responders will be notified. Emergency medical coverage is available via the emergency room that is approximately 1.5 miles from the CSTP.

We screen for pregnancy among participants to reduce these risks and inform participants of risks to the baby, during pregnancy/delivery, as well as negative fertility-related effects. We advise participants not to become pregnant or father a baby during the study.

We also inform participants of unknown negative effects related to study participation. Being open about these risks is an important step.

We also monitor the research literature and public health authorities for any changes in risks associated with cigarette smoking and/or ECIG use.

3. * **Describe any potential risks or harms to a community or a specific population based on study findings (e.g. information that could be stigmatizing or derogatory):**
   None

4. **Where appropriate, discuss provisions for ensuring necessary medical, professional, or psychological intervention in the event of adverse events to the subjects:**
   Research personnel are trained to alert the research nurse if heart rate continually exceeds 120 beats per minute, if systolic BP continually exceeds 160 mm Hg, or if diastolic BP continually exceeds 100 mm Hg. Individuals whose heart rate and/or BP levels remain elevated will be monitored by the research nurse and if, necessary, emergency responders will be notified. Emergency medical coverage will be available via the emergency room that is 1.5 miles from the CSTP.

   Individuals whose BP levels are elevated (>=140 mmHg systolic or >=90 mmHg diastolic) during baseline screening or at a session will be provided with a blood pressure information sheet by the research staff (see study document). This sheet will be provided at the first instance of elevated blood pressure observed during the study.

5. * **Describe criteria for when the investigator would withdraw an individual participant from the study; such as safety or toxicity concerns, emotional distress, inability to comply with the**

protocol, etc.:
Participants may be withdrawn from the study if the PI or study nurse has any safety concerns (such as high blood pressure or heart rate) during sessions.

If participant cannot complete a session due to unforeseen circumstances (i.e., family emergency), we allow multiple attempts, but do not have a specified number of attempts that are allowed, as it depends on the circumstances of each participant.

6. * **Summarize any pre-specified criteria that would trigger the investigator/sponsor/monitoring committee to stop or change the study protocol due to safety concerns:**
We do not have any prespecified criteria for stopping or changing the study protocol due to safety concerns.

Data and Safety Monitoring
Data and safety monitoring is a system for checking the study's data at regular intervals over the study period to identify and address issues that could affect the safety of research participants. This requirement is in accordance with 45 CFR 46.111.

The purpose of data and safety monitoring plan is to set forth study team procedures for monitoring/addressing:
- Participant safety (physical, psychological, etc.)
- Data validity
- Early stopping (termination) based upon changes in risks and benefits.

7. * **Indicate if this study will have a Data Safety Monitoring Board (DSMB) or a Data Safety Monitoring Plan (DSMP): [Required for all greater than minimal risk studies]**

- [ ] DSMB
- [x] **DSMP**
- [ ] No DSMB/DSMP [Note: This response is not applicable for greater than minimal risk studies]

8. * **Describe your Data Safety Monitoring Plan for monitoring the study's data to ensure the safety of participants. This plan should include (but is not limited to) the following elements:**
1. Who will monitor data
2. What data and/or processes will be reviewed
3. When and how frequently monitoring will occur
4. What report/documentation will be submitted to the IRB at the time of continuing reviews

See the help text for additional guidance.

1. Who will monitor data: The Co-PIs (Drs. Cobb and Barnes) and the medical monitor (Dr. Lipato)

2. What data and/or processes will be reviewed:
-Baseline sociodemographic characteristics of enrolled study participants
-Reasons for ineligibility following in-person screening
-Retention and disposition of study participants including any complaints about the study and reasons for participant withdrawal
-Responses to the pre-session symptom checklist
-Protocol deviations/violations
-Any other regulatory issues
-Adverse events
-Serious adverse events
-Unanticipated problems

3. When and how frequently monitoring will occur:
Any adverse events and protocol deviations/violations that occur during the study sessions will be monitored and documented by the research staff and communicated as soon as possible to PI/medical monitor for review/response. We will follow VCU IRB reporting requirements for all adverse events and protocol deviations/violations that may occur.

We also will review all of the items listed in #2 in a summary report annually.

4. What report/documentation will be submitted to the IRB at the time of continuing reviews:
A summary report that includes all of the items listed in #2 will be submitted to the IRB at the time of the continuing reviews.

Privacy

Privacy refers to an individual's right to control how others view, record, or obtain information about them. When privacy is violated it can involve such things as

- Being asked personal questions in a public setting;
- Being publicly identified as having a particular characteristic or diagnosis;
- Being seen entering a place that might be stigmatizing;
- Being photographed, videotaped or observed without consent;
- Disclosure of personal information to unauthorized people

Privacy is not the same as confidentiality because privacy protections apply to people, and confidentiality protections apply to data. Confidentiality protections should be described on the Data Confidentiality page of this form, not here.

Instructions for this page:

Select all the applicable ways that the research team will protect participants' privacy throughout the course of the study. The options listed include some of the most common best practices. Not all will be applicable to every study.

****The IRB will expect studies to operationalize all selected checkboxes into the conduct of the research.**

To elaborate on any response, also click the "Other Protections" checkbox to provide further explanation in the last free-text question.

Read the entire page before filling out the form.

1. * **Protections when conducting one-on-one in-person interventions or interactions (for groups see Q2 below):**
   - [x] **Conducting study activities in locations that maximize privacy (limited people around, closing doors, drawing drapes around beds, monitoring voice volume, etc.)**
   - [ ] Verifying identity before discussing personal information.
   - [ ] Asking the participant if they are comfortable answering questions in that location
   - [ ] Asking the participant if they are comfortable with having other people present (if any)
   - [ ] Moving away from other people when conducting activities in public spaces or offering a private space
   - [ ] Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing) if uncomfortable verbally responding
   - [ ] Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics
   - [x] **Other protections not listed in this question – describe below**
   - [ ] N/A – study has no in-person interventions or interactions with participants

2. * **Protections when conducting group interventions or interactions:**
   - [x] **Conducting study activities in locations that maximize privacy (limited people passing by, closing doors, monitoring voice volume, etc.)**
   - [ ] Moving to a more private area to answer questions or to discuss concerns
   - [ ] Discussing privacy with the participants and the importance of not talking outside the group about what other people say during the group session
   - [ ] Allowing participants to use a pseudonym or limiting use of individuals' names during the group activity
   - [ ] Asking everyone in a public group setting (e.g. classrooms, workshops) to turn something in (blank or filled) so participants do not have to self-identify when turning in materials
   - [ ] Collecting paper forms in a closed box or envelope rather than passing to others or leaving in an open area
   - [x] **Limiting participant identifiers that would be visible on paper documents (i.e. using study IDs instead of direct identifiers)**
   - [ ] Allowing people to distance themselves from other participants during group activities
   - [ ] Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing instead of speaking)

- [ ] Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics
- [ ] Ensuring non-participating individuals are not captured on recordings or in photos
- [ ] Other protections not listed in this question – describe below
- [ ] N/A – study has no group interventions or interactions

3. * **Protections when conducting remote interventions or interactions (e.g. phone, text, email, video-conference, tele-health, online, etc.):**
- [x] **Conducting study activities in locations where study staff can maximize their own privacy (limited people around, closing doors, monitoring voice volume, etc.)**
- [ ] Leaving/sending generic messages that avoid using study and participant identifiers, such as names, study titles, clinics, study topics, etc.
- [x] **Obtaining permission prior to sending text messages**
- [ ] Advising the participant to move to a location where they are comfortable answering questions and will not be overheard - incorporate this instruction into your study materials
- [ ] Advising online participants to complete the activity at a time and location where they will be comfortable answering questions - incorporate this instruction into your study materials
- [ ] Ensuring non-participating individuals are not captured on recordings or in photos
- [ ] Offering other options of ways to complete the activity (i.e. online, paper, phone) if more privacy is desired
- [ ] Offering a way to save and return later to the online activity if privacy is compromised
- [ ] Other protections not listed in this question – describe below
- [ ] N/A – study has no remote interventions or interactions with participants

4. * **Protections when mailing study materials to/from participants:**
- [ ] Obtaining permission to mail study materials
- [ ] Confirming/verifying the accuracy of addresses before mailing items
- [ ] Ensuring the participant is able to personally receive mailed materials and has a way to protect their own privacy if they do not want others to know they are receiving research communications (i.e. notifying participants of when to expect it)
- [ ] Using return address labels and document headers that avoid study identifiers, such as study names, clinics, study topics, etc.
- [ ] Avoiding or limiting use of participant identifiers and health information on mailed documents (i.e. using study IDs instead of direct identifiers)
- [ ] Providing a return mailing address label or pre-addressed envelope to ensure returned items are sent to the correct address
- [ ] Communicating receipt of mail from participants and/or asking them to notify you when they mail it to ensure study documents are not lost in transfer
- [ ] Offering other options of ways to complete the activity (i.e. by phone or online) if desired
- [ ] Other protections not listed in this question – describe below
- [x] **N/A – not mailing any materials to/from participants**

5. * **Protections when analyzing or disseminating study data** *Applicable to all studies***:**
- [x] **Working only in locations where the study team can ensure privacy (not working in close proximity to non-study personnel, closing doors, closing/putting away documents/files before leaving, etc.)**
- [x] **Securing physical materials only in locations that ensure privacy (access limited to authorized study personnel)**
- [x] **Only sharing data/specimens in accordance with the Sharing Plan outlined in this smartform**
- [ ] Obtaining explicit parental permission before disseminating or sharing recordings or photos of children
- [ ] Blurring/redacting/hiding faces and other identifiable features/marks (tattoos, scars, birthmarks, distinctive voice, etc.) in recordings or photos prior to disseminating or sharing
- [ ] Only publishing or presenting aggregate results or findings (i.e. no individual-level information)
- [ ] Taking additional steps to protect participant identities when publishing or presenting individual-level information, quotations, results, images – describe below
- [ ] Other protections not listed in this question – describe below

6. **Describe any other way(s) that the research team will protect participants' privacy. *See the help text for additional guidance*.**

Participants' privacy and comfort will be addressed throughout the course of the study. During the intake process and session, participants will be seated in a private room. All study procedures will take place behind closed doors. We will use Zoom (like an intercom) to communicate with participants from outside of the session room, but will not use a camera for the computers in the session rooms, nor will the participants' name be entered into Zoom. We will also use a password-protected Zoom session. Participants will be informed that they may withdraw from the research study should they find any research procedures unacceptable. All participants and data will be treated with professional standard of confidentiality. Data are identified by numeric code only and stored under double lock or in REDCap. Participants' names are not directly linked to data. Briefly, a numeric code is assigned to each participant when they provide informed consent, and the part of the numeric code relates to the order in which the individual consented. This numeric code appears on all data. Access to the key and the consent documents is restricted to study investigators and staff: these individuals perform the informed consent and conduct the study with the participants so they already know who the participants are and observe the participants as data are collected. Participants' research-related information will be withheld, consistent with the law, unless permission is given to release such information. Effectiveness is indexed by previous experience: we have used these procedures for over 20 years and have not had a single incident in which a participants' confidential information has been compromised.

In addition, the way in which the referral program will be administered (with participants who complete this study being given cards with alphanumeric codes linked to their names/e-mail addresses) reduces the risk of a loss of privacy, as the original participant will not be told who brought in the card(s).

Data Confidentiality and Storage

Confidentiality refers to the way private, identifiable information about a participant or defined community is maintained and shared. It describes how the study's research materials (data, specimens, records, etc.) are protected from unauthorized access.

Instructions for this page:
Select all the ways that the research team will keep the study materials and data confidential throughout the course of the study. Not all will be applicable to every study.
To elaborate on any response, also click the "Other Protections" checkbox to provide further explanation in the last free-text question.

Read the entire page before filling out the form.

1. * **Protections for paper research materials:**
   - [x] **Maintaining control of paper documents at all times, including when at an off-campus location**
   - [x] **Limiting or avoiding use of participant identifiers on paper documents (i.e. using study IDs instead of direct identifiers)**
   - [x] **Storing paper documents in a secure location accessible only to authorized study personnel**
   - [ ] Promptly transcribing, scanning, or abstracting data from paper into electronic platforms with destruction of the paper copy
   - [x] **Proper destruction of paper records (and obtaining prior permission when required) in accordance with VCU Records Management policies**
   - [x] **Other protection not listed in this question – describe below**
   - [ ] N/A – no paper research materials

2. * **Protections for research specimens:**
   - [x] **Maintaining control of specimens at all times, including when at an off-campus location**
   - [x] **Storing specimens in a secure location accessible only to authorized study personnel**
   - [x] **Labeling specimens with subject ID or other coded information instead of direct identifiers**
   - [x] **Final destruction of specimens will be in accordance with VCU policies and specimen containers will be devoid of any identifiable information**
   - [ ] Other protection not listed in this question – describe below
   - [ ] N/A – no research specimens

3. * **Protections for electronic files/data - See https://ts.vcu.edu/about-us/information-security/data-management-system/**
   - [x] ***Required for all studies* Use VCU-approved methods of data storage, transmission, and transfer (see https://dms.vcu.edu)**
   - [x] **Remotely accessing VCU network storage to store data when at off-campus locations**
   - [x] **Ensuring unauthorized individuals who might share a device do not have access to study materials (e.g. individual logins, separate accounts)**
   - [x] **Using VCU-approved data collection tools and apps (e.g. REDCap) and storing exported analysis files in VCU-approved storage locations (see https://dms.vcu.edu)**
   - [ ] When using non-VCU-approved electronic data collection tools, storage locations, data transfer platforms, and mobile apps (e.g. Dropbox, Box, Survey Monkey, Fitbits, novel apps, multi-site data collection platforms):
     • consulting with VCU Information Security on proper data management (see https://ts.vcu.edu/askit/essential-computing/information-security/);
     • advising participants about the terms of use and privacy policies of those sites/apps;
     • limiting or avoiding use of identifiers; and
     • removing data promptly from the external location after transferring it to a VCU storage location
   - [x] **De-identifying the research data by replacing subjects' names with assigned subject IDs**
   - [x] **Storing the study's linkage key in a password-protected and VCU-approved storage location (see https://dms.vcu.edu)**
   - [ ] When analyzing particularly sensitive information, using computers that are unconnected from the internet.
   - [x] **Proper destruction of electronic records (and obtaining prior permission when required) in accordance with VCU Records Management policies**

- [x] **Other protection not listed in this question – describe below**

4. * **Protections for computers and research devices/apps that are <u>provided to participants</u> for use in the study and taken out of the lab (i.e., giving participants a phone or iPad to take home, wearable trackers, apps, etc.):**
   - [ ] Transferring data promptly from the device/app given to the participant to a VCU storage location
   - [ ] Setting strong passwords on computers and research devices (when applicable) that leave VCU with participants
   - [ ] Device/app set up by VCU Information Security
   - [ ] When providing devices or mobile apps to children, informing parents about the settings and how to manage them (if applicable), internet access, and any other installed apps on the device
   - [ ] Other protection not listed in this question – describe the device/app and protection below
   - [x] **N/A – no computers or devices/apps being provided for participant use outside the lab**

5. * **Protections for email/online communications**
   - [x] **Only using VCU/VCU Health email addresses for study-related communications**
   - [x] **Only using VCU/VCU Health–approved methods of teleconferencing or video conferencing (e.g. Zoom) (for studies involving HIPAA, contact VCU or VCU Health Information Security [as appropriate] about HIPAA-compliant systems)**
   - [x] **Other protection not listed in this question – describe below**
   - [ ] N/A – no email/online communications

6. **Specify any other places where this study's paper and electronic research data and/or physical specimens will be stored and any other ways they will be secured from improper use and disclosure.**

   See the help text for additional guidance.
   Any paper based records will be kept in a locked cabinet in the CSTP lab in a locked room with entry to the lab secured by a keypad and only accessed by authorized study personnel.

   An electronic copy of each consent form will be stored in Veeva Site Vault per new requirements for clinical studies.

   All computers and storage devices will be kept in locked cabinets and/or within locked laboratory rooms. Electronic records will be made available only to those personnel in the study through the use of access controls (passwords). Identifiers will be removed from study-related data and data will be coded with a key stored in a separate, secure location. Electronic data (with study IDs only) is stored in REDCap and/or in excel spreadsheets that are saved either on hard drives and/or a VCU server. Data from the online registry, as well as the in-person screen and from sessions will be stored in and can only be accessed through the password-secured system REDCap. Only approved CSTP staff, faculty, and students will have keys and/or electronic access to this information.

   Identifiers will be removed from study-related data and data will be coded with a key stored in a separate, secure location in a locked cabinet. All web-based surveys will have data secured via passwords. De-identified data will be transferred to secure servers that are password protected for data cleaning and analysis. No data will be stored under any other departments.

   Some data are recorded using software separate from REDCap. These data are stored on password protected computers and backed-up on secure datakeys that require a password (IronKey).

   Software types are as follows:
   REDCap for self-report data, including baseline and session measures which include subjective questionnaires, and some abuse liability measures (see the document "Drug Purchase Tasks (DPT)")

   Hyperterminal is used to collect physiological data. The data file is stored locally, under a username and password protected profile. It is then copied to secure storage locations (such as Ironkey or R-Drive) after each session.

   The Minute Discounting Task (see, 'Baseline Discounting Task - MDT' document) is collected at baseline or in-person screening visits via Qualtrics. Data is stored within Qualtrics under usernames and passwords assigned to some lab staff.

   Urine samples are labeled with participant code numbers and stored in a -80 degree freezer in a locked laboratory space. The samples are stored separately from identifying information (consent forms).

7. * **If research data/specimens will be sent/released to person(s) or group(s) outside of the VCU study team or the PI's department for the conduct of this protocol (not for future sharing),**
   1) identify the data/specimen recipient(s) along with their VCU department or other institutional or organizational affiliation(s).
   2) give a description of what identifiers and/or codes will accompany the data/specimens.
   If data/specimens are not being sent/released outside of the VCU study team or the PI's

department, state that:
Data with identifiers will not be released to any person or group outside the study team.

8. * **Select all identifiers that will be collected <u>at any time</u> as part of this study (including for recruitment, data gathering, data analysis, etc.), even if the data will eventually be anonymized:**

- [x] **Names**
- [x] **Geographic Locators Below State Level**
- [x] **Social Security Numbers**
- [x] **Dates (year alone is not an identifier)**
- [ ] Ages over 89 (age under 89 is not an identifier)
- [x] **Phone Numbers**
- [ ] Facsimile Numbers
- [x] **E-mail Addresses**
- [ ] Medical Record Numbers
- [ ] Device Identifiers
- [ ] Biometric Identifiers
- [ ] Web URLs
- [ ] IP Addresses
- [ ] Account Numbers
- [ ] Health Plan Numbers
- [ ] Full Face Photos or Comparable Images
- [ ] License/Certification Numbers
- [ ] Vehicle ID Numbers
- [x] **Other Unique Identifier**
- [ ] No Identifiers
- [ ] Employee V#

9. **If "Other Unique Identifier" was selected above, describe the identifiers:**
Participant ID.

10. * **If the study will code (i.e. de-identify) the research data by replacing subjects' names and/or other identifiers with assigned subject IDs, explain the following aspects of the coding process:**

- The process for how subject IDs will be generated/assigned (e.g. random, sequential)
- Whether there will be a key that links the subject ID with direct identifiers. If there will be no linkage key, state that.

If a key will be created, describe
- The place where the key will be stored
- The role(s) of all individuals who will have access to the key
- When the key will be destroyed

See the help text for guidance.
Data are identified by numeric code only. Participants' names are not directly linked to data. Briefly, a numeric code is assigned to each participant when they provide informed consent, and the numeric part of the code relates to the order in which the individual consented. This participant numeric code appears on all subsequent documents/data forms. A key is maintained in the study binder so that we can demonstrate that a particular data set is associated with a particular consent document. The key and consent documents are stored separately from each other and separately from all data (under double lock or in REDCap). Access to the key and the consent documents is restricted to study investigators, staff, and students: these individuals perform the informed consent and conduct the study with the participants, so they already know who the participants are and observe the participants as data are collected. Data keys will be destroyed at the end of the study once the minimum time required for data retention has been met per VCU Data Retention Policy and/or sponsor retention requirements. De-identified data may be stored indefinitely.

Data Retention

1. * **Select all of the ways that individually identifiable information obtained during pre-screening and/or screening will be handled for individuals who DO NOT qualify for the study:**
   - [ ] N/A - study does not require screening procedures
   - [ ] Immediately destroy the information and identifiers (no data collected)
   - [ ] Immediately destroy the identifiers connected with the data (anonymization)
   - [ ] Store until the end of study & then destroy
   - [ ] Use as "screening failure" data by members of the study team
   - [ ] Provide to others outside of the research team (with the participant's permission)
   - [ ] Request permission from participant to maintain and use the identifiable information
   - [x] **Other**

2. **If Other, explain how the information will be handled.**
   All in-person screening procedures occur after participants have consented to the full study. All data collected may be included in reports/presentations/publications including reasons for screening failure among enrolled participants.

3. * **Will participants be able to withdraw their data (paper, electronic, or specimens) from the study (e.g. ask that it be destroyed or returned) if they no longer wish to participate? (FDA-regulated studies should select No – see help text)**
   - ○ Yes
   - ● **No**

4. * **What will happen to the research materials (e.g. data, specimens, documents, etc.) when the research has been completed?**
   - ● **Stored indefinitely with identifiers removed**
   - ○ Stored indefinitely with identifiers attached
   - ○ Destroyed at the end of study once the minimum time required for data retention has been met per VCU Data Retention Policy and/or sponsor retention requirements
   - ○ Destroyed when notified by sponsor but not less than the minimum time required for data retention per VCU Data Retention Policy
   - ○ Other

5. * **Will audio/video recordings and full face photographs be destroyed?**
   - ○ Yes
   - ● **No**

6. **If yes, describe at what point and how recordings will be destroyed:**

7. **If no, explain why the recordings need to be maintained:**
   There will be no recordings.

Sharing Plan

This page addresses times when investigators may be required to share information about participants or may desire to share their research information/specimens with the aim of advancing science. This page creates a plan for when and how information/specimens could be shared.

Try to anticipate all reasonably foreseeable sharing so that the consent document can also reflect that information. However, it is acceptable to amend this page later and explain either how re-consent of previously and currently enrolled participants will occur or why re-consent should not be required.

The IRB reviews this page against the consent document (if one exists) to demonstrate the ethical principle of Respect for Persons by confirming that plans for sharing do not go against what participants would understand about the use of their data/specimens.

The IRB also ensures there are adequate protections for the privacy of participants and the confidentiality of participants' data/specimens when data is shared with others.

1. * **Is it likely investigators could discover information about child/elder abuse or neglect that would require mandatory reporting by the investigators or staff?**

   The Code of Virginia requires that most medical personnel and all employees of institutions of higher education report suspected child/elder abuse or neglect.

   ○ Yes
   ● **No**

2. * **Is it likely investigators could discover a previously unknown reportable disease or condition that would require mandatory reporting by the investigators or staff (i.e., HIV , coronavirus, hepatitis, etc.)?**

   ○ Yes ● **No**

3. * **Will the sponsor or investigator obtain a Certificate of Confidentiality for this study?**

   Certificates of Confidentiality (CoC) are issued by the National Institutes of Health (NIH), the FDA and CDC to protect identifiable research information from forced disclosure. All human subject research studies regardless of funding can qualify to receive a CoC. A CoC is automatically issued for research that was ongoing on December 13, 2016. or initiated after that date. For more information, see https://humansubjects.nih.gov/coc/

   ○ No – Will not obtain CoC for this study
   ● **Yes – CoC has been obtained or issued automatically**
   ○ Yes – CoC request is pending

4. * **Select the way(s) that information or biospecimens (including DNA) may be used <u>by the VCU PI or VCU study team for other future research projects</u> (i.e. analyses beyond/apart from the aims of this study)?**
   See help text for definitions.

   ☐ Will use directly identifiable information or specimens.

   ('Directly identifiable' means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research is treated as a registry by the VCU IRB. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. VCU IRB studies will be asked more questions about this on a later page)

   ☐ Will use de-identified or indirectly identifiable information or specimens.

   ('De-identified' means that a linkage/key code exists that links identifiers to data/specimens. When the researcher holds both the data and the key, the VCU IRB considers the subjects to be readily identifiable. Maintaining identifiable data for future research uses is treated by the IRB as a registry. The IRB must approve

the new research use in an amendment to this study or as part of a new study before the project is initiated. VCU IRB studies will be asked more questions about this on a later page)

Will use anonymized information or specimens.

☑ *('Anonymized' means that 1) no linkage/key codes exist that link identifiers to data/specimens; and 2) subjects cannot be readily identified, i.e. no direct or indirect identifiers or identifiable combinations of variables. The VCU IRB considers uses of anonymized data/specimens to not be human subject research.)*

Will use aggregate results (summary-level results), not individual-level information or specimens.

☐ *(The VCU IRB considers uses of aggregate data to not be human subject research because there are no individual subjects.)*

Will contribute to an existing registry or repository

☐ *(VCU IRB studies will be asked more questions about this on a later page.)*

☐ Will not use information/specimens for purposes beyond this study.

☐ Not sure and will submit an amendment when known

☐ Other use(s) of individual-level information in a way not listed above

5. * **Select the way(s) the VCU PI/study team may share information or biospecimens (including DNA) with other researchers who are not on this study team (i.e. for analyses beyond/apart from the aims of this study).**
See help text for definitions.

Will share directly identifiable information or specimens with other researchers.

☐ *('Directly identifiable' means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research uses is treated by the VCU IRB as a registry. The data recipient's use of identifiable data would require them to obtain IRB review. VCU IRB studies will be asked more questions about this on a later page.)*

Will share de-identified or indirectly identifiable information or specimens with other researchers.

☐ *('De-identified' means that a linkage/key code exists that links identifiers to data/specimens. The VCU researcher maintains the key but does not share it with any other researchers. The recipient's use of de-identified data/specimens may not be human subject research if there is documentation that the key will never be shared with the recipient, but they should check with their own IRB about review requirements. VCU IRB studies will be asked more questions about this on a later page.)*

Will share anonymized information or specimens with other researchers.

☑ *('Anonymized' means that 1) no linkage/key codes exist that link identifiers to data/specimens; and 2) subjects cannot be readily identified (i.e. no direct or indirect identifiers or identifiable combinations of variables). The VCU IRB considers uses of anonymized data/specimens by other researchers to not be human subject research, but the recipient should check with their own IRB about review requirements.)*

Will only share aggregate results (summary-level results), not individual-level information or specimens.

☐ *(The VCU IRB considers uses of aggregate data to not be human subject research because there are no individual subjects. The data recipient should check with their own IRB about review requirements.)*

☐ Will contribute to an existing registry or repository (VCU IRB studies will be asked more questions about this on a later page.)

☐ Will submit data to an NIH genomic data repository (VCU IRB studies will be asked more questions about this on a later page.)

☐ Will not share information/specimens with other researchers.

☐ Not sure and will submit an amendment when known

- [ ] Other sharing of individual-level information with other researchers

6. * **Since you responded in a question above that you may use or share anonymous, individual level data, indicate why the proposed use or sharing of anonymous data/specimens is not inconsistent with what participants would have reasonably understood from the consent document about the uses of their information. (Select all that apply.)**

- [x] **The consent form states that after identifiers are removed, information or specimens could be used for future research studies without additional informed consent from the subject (this is a new element of consent included in consent templates as of May 2018)**
- [ ] The consent form or exempt information sheet is silent about whether/how information or specimens could be used for future research studies.
- [ ] The information or specimens were/will be obtained under a waiver of informed consent, waiver of HIPAA authorization, or an exempt study that did not use an information sheet.
- [ ] Other reason why anonymous use/sharing is not inconsistent with the consent document

7. * **The Principal Investigator certifies that prior to releasing an anonymized dataset or anonymized specimens the following conditions will all be met:**

- all 18 HIPAA identifiers (including all dates) will be removed;
- all indirectly identifiable data elements (unusual, rare, uncommon data) will be removed, grouped, suppressed, or otherwise transformed to no longer be readily identifiable;
- a different subject ID will be assigned than the one used for the main study and a linkage key will not be kept; and
- the PI will review the dataset/specimens to confirm that the remaining information could not be used alone or in combination with any other information to re-identify the participants represented in the data.

***See help text for more information*.**

- (●) **Yes**
- ( ) No

8. * **The Principal Investigator certifies that after the study has been closed with the VCU IRB, the following conditions will be met whenever individual level research information and/or specimens are used or shared:**

- The identities of participants who are represented in the dataset/specimens will not be readily ascertainable or otherwise re-identifiable by the recipient;
- If a linkage/code key is created, it will be maintained at VCU and not shared with the recipient under any circumstances;
- The PI will have no knowledge that the remaining information could be used alone or in combination with any other information to identify the individuals represented in the data; and
- The PI agrees to abide by this sharing plan even after the study has been closed with the VCU IRB.

- (●) **Yes**
- ( ) No
- ( ) N/A - No sharing will occur

9. **If the Certificate of Confidentiality has been obtained by the PI, upload it here:**

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Informed Consent	P3 TASTE_Informed Consent_CLEAN_1.29.2024.pdf	0.15	2/20/2024 10:22 AM	Rabia Imran	Consent/Assent/Information Sheet	Yes
View	Consent - Tool	P3TASTE_Consent_Presentation_1.29.2024.pptx	0.06	1/30/2024 1:34 PM	Rabia Imran	Consent/Assent/Information Sheet	Yes
View	Social Media Plan	P3-TASTE Social Media Plan_10.2.2023.docx	0.01	10/2/2023 3:29 PM	Caroline Cobb Amey	Recruitment/Advertising	Yes
View	Social Media and Craigslist Ads	P3-TASTE_facebook and craiglist ads_10.2.2023.docx	0.01	10/2/2023 3:29 PM	Caroline Cobb Amey	Recruitment/Advertising	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Substance Use Resources Handout	CSTP Substance Use Resources_8.11.2023.docx	0.01	8/11/2023 5:11 PM	Caroline Cobb Amey	Other	Yes
View	Subjective Measures	P3-TASTE-Session Subjective Measures_CLEAN_08.09.2023.doc	0.03	8/11/2023 5:10 PM	Rabia Imran	Research Measure	Yes
View	P3 TASTE Advertisement for CSTP Website	P3 TASTE - CSTP Website Study Description_CLEAN_08.08.2023.docx	0.05	8/11/2023 5:09 PM	Rabia Imran	Recruitment/Advertising	Yes
View	Presession Symptom Questions	P3-Presession symptom Checklist-CLEAN_08.09.2023.docx	0.05	8/11/2023 5:08 PM	Rabia Imran	Research Measure	Yes
View	Baseline Self Report Physio Measures	P3-TASTE_Baseline forms All_CLEAN_8.11.2023.docx	0.06	8/11/2023 5:07 PM	Rabia Imran	Research Measure	Yes
View	Text, Email, Call Scripts	P3-TASTE_Phone_e-mail_text scripts_08.09.2023_CLEAN.docx	0.10	8/11/2023 5:06 PM	Rabia Imran	Study reminders/communications	Yes
View	Referral Program Card Template	P3_Referral program card_06.02.2023_CLEAN.docx	0.03	6/13/2023 1:48 PM	Rabia Imran	Recruitment/Advertising	Yes
View	COVID-19 Questions	COVID_Questions_P3_no longer using.docx	0.02	6/13/2023 1:35 PM	Rabia Imran	Other	Yes
View	P3 Taste_ETM	P3-TASTE_Measures_ETM__no longer using.docx	0.04	6/13/2023 1:35 PM	Rabia Imran	Research Measure	Yes
View	Tobacco Cessation Resources Handout	Cessation_handout_RI_04.29.2021.pdf	0.01	2/1/2023 3:32 PM	Caroline Cobb Amey	Other	Yes
View	U54 Grant Application Without Budget	U54 Grant Application BUDGET PAGES DELETED FOR IRB.pdf	0.01	10/28/2022 2:17 PM	Rabia Imran	Funding Proposal	Not Applicable
View	CP-DPT & DPT	P3-TASTE Drug Purchase Tasks_9.2.2022.docx	0.01	10/28/2022 2:03 PM	Rabia Imran	Research Measure	Yes
View	CP-DPT & DPT - Tool	DPT_CDPT presentation_10.28.2022.pptx	0.01	10/28/2022 2:03 PM	Rabia Imran	Research Measure	Yes
View	Subjective Measures - Tool	Subjective Measures presentation_10.28.2022.pptx	0.01	10/28/2022 2:00 PM	Rabia Imran	Research Measure	Yes
View	Barnes Biosketch	P3 Barnes biosketch 06.22.17.FINAL.docx	0.01	10/28/2022 1:55 PM	Rabia Imran	CV/Biosketch	Not Applicable
View	Lipato Biosketch	Lipato Biosketch.pdf	0.01	10/28/2022 1:54 PM	Rabia Imran	CV/Biosketch	Yes
View	Caroline Cobb (Amey) CV	CV_Cobb_August 2022.docx	0.01	10/28/2022 1:54 PM	Rabia Imran	CV/Biosketch	Yes
View	Baseline Discounting Task - MDT	P3_TASTE_Discounting Task_11.7.2018.pdf	0.01	10/28/2022 1:54 PM	Rabia Imran	Research Measure	Yes
View	U54 Project 3 Grant Docs	U54_Project 3 only docs.pdf	0.01	10/28/2022 1:53 PM	Rabia Imran	Funding Proposal	Not Applicable
View	CSTP Parking Map	CSTP Parking Map.docx	0.01	10/28/2022 1:52 PM	Rabia Imran	Other	Not Applicable
View	Criticare HR/BP Manual	Criticare_Vitalcare_506N3_-_Service_manual.pdf	0.01	10/28/2022 1:52 PM	Rabia Imran	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Expired Air CO Manual	CO Monitor Manual.pdf	0.01	10/28/2022 1:51 PM	Rabia Imran	Other	Not Applicable
View	Information about Blood Pressure	BP results P3 flux 8.22.2022.docx	0.01	10/28/2022 1:51 PM	Rabia Imran	Study reminders/communications	Yes
View	CSTP Registry Consent and Survey	CSTP Registry Consent Form and Questions.pdf	0.01	10/19/2022 3:27 PM	Caroline Cobb Amey	Other	Not Applicable

Pertinent Results and Incidental Findings

1. * **Is it likely investigators could discover a participant's previously unknown condition (e.g. pregnancy, disease, suicidal thoughts, wrong paternity, genetic results, or other findings that may be of importance to health or well-being) or if a participant is engaging in illegal or reportable activities:**
   - (●) **Yes**
   - ( ) No

2. * **Describe what possible pertinent results or incidental findings stemming from research-only procedures may be discovered.**
   During screening, we assess blood pressure.

   During screening, we assess if those whose sex assigned at birth was female are pregnant.

   During screening, we ask questions about cannabis use and other illicit drugs.

   During screening and at the beginning of a session, we ask about respiratory and gastrointestinal symptoms.

3. * **Explain what actions or procedures research personnel should take to inform the PI of such a discovery :**
   Findings for blood pressure and pregnancy will be communicated to participants verbally (and via a paper document for blood pressure only) during the in-person screening visit (and for blood pressure, possibly at other visits). These findings will only be communicated to the participant and will be communicated by the study staff conducting the screening and/or session. In the event of high blood pressure or a positive pregnancy test, the study staff will communicate this information and advise the participant to seek treatment.

   For blood pressure specifically, individuals whose blood pressure levels are elevated (>=140 mmHg systolic or >=90 mmHg diastolic) during screening or at a session will be provided with a blood pressure information sheet by the research staff (see study document). This sheet will be provided at the first instance of elevated blood pressure observed during the study.

   If a participant reports cannabis use, although some aspects of cannabis use may be illegal (such as possession or more than very small quantities), the research staff will not take any actions. This study has a certificate of confidentiality, which provides additional protections for participants.

   Individuals who engage in illicit drug use in the past month will not be eligible for an in-person screen or to participate in the clinical laboratory portion of the study. We will provide a Substance Use Resources Handout to those who disclose illicit drug use other than marijuana/cannabis.

   Answers given about respiratory and gastrointestinal symptoms will be compared to the participants' previous answers and if any symptoms have increased, Dr. Lipato will be asked to review the symptoms. In some cases, we may ask Dr. Lipato to determine if a session can proceed.

4. * **Will findings be disclosed to participants and/or any other person/group outside of the study team?**
   - (●) **Yes**
   - ( ) No

5. * **Describe a communication plan addressing:**
   1. What criteria will be used to determine which pertinent and/or incidental findings will be communicated, including the following for health related findings:
   --- The reliability of the tests/images, such as being done in a CLIA-certified lab,
   --- Whether the meaning and significance of the findings are known,
   --- Whether the findings reveal a significant risk of a serious health condition,
   --- Whether there is an accepted treatment for the health condition revealed by the findings, and
   --- The risks both of knowing and not knowing the findings, including risks to family members from genetic testing results.
   2. What information will be provided during the consent process about the plans for communicating pertinent and/or incidental findings;
   3. Whether the participants will be given the option of refusing communication of some or all

types of pertinent and/or incidental findings to themselves, their family members, and/or any other individuals or groups; and

4. To whom and by whom the findings will be communicated, when, and how.

In the event of high blood pressure or a positive pregnancy test or other responses to the presession symptom checklist of concern, the study staff will communicate this information to the appropriate party according to Virginia state law, seek guidance from the medically responsible investigator (MRI) and/or PI, and at the recommendation of the MRI and/or PI, at times, advise the participant to seek treatment.

Findings for blood pressure and pregnancy will be communicated to participants verbally (and via a paper document for blood pressure only) during the in-person screening visit. These findings will only be communicated to the participant and will be communicated by the study staff conducting the screening. In the event of high blood pressure or a positive pregnancy test, the study staff will advise the participant to seek treatment.

For blood pressure specifically, individuals whose blood pressure levels are elevated (>=140 mmHg systolic or >=90 mmHg diastolic) during screening or at a session will be provided with a blood pressure information sheet by the research staff (see study document). This sheet will be provided at the first instance of elevated blood pressure observed during the study.

The reliability of the blood pressure monitor is not known, nor is the reliability of the pregnancy tests we use.

The blood pressure measurement could reveal a significant health risk, depending on how high it is.

There is accepted treatment for high blood pressure.

There are no risks to knowing about high blood pressure or pregnancy.

Participants do not have the option of refusing communication about their blood pressure or pregnancy test results.

Any adverse events may be reported to the study sponsor at FDA/NIH as needed/per their request.

Any information about adverse events reported to individuals outside of the study team will not include participants' names, DOBs, or other identifying information. Currently, the consent form indicates that such data might be shared with the study sponsor:

"Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring, and overseeing this study:
-The study Sponsor, representatives of the sponsor, and other collaborating organizations
-Representatives of VCU and the VCU Health System
-Officials of the Department of Health and Human Services"

Risk Benefit Complete

Protocol Progress:
- **INITIAL SETUP**
- **BACKGROUND, RATIONALE & GOALS**
- **RESEARCH PLAN**
- **CONSENT PLAN**
- **RISKS, PRIVACY & CONFIDENTIALITY**

⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Populations with Special Considerations

1. * **Check all participant groups that will be either**

   a) Specifically included in this study or

   b) Discernable in the research data/specimens.

   (Selections will branch)

- [ ] Children
- [ ] Emancipated minors
- [ ] Wards of the State
- [ ] Pregnant women or fetuses
- [ ] Neonates or Post-delivery Materials
- [ ] Prisoners
- [ ] Decisionally Impaired Adults
- [ ] VCU / VCUHS students or trainees
- [ ] VCU / VCU Health System employees
- [ ] Individuals with limited English proficiency
- [ ] Active military personnel
- [ ] Student populations in K-12 educational settings or other learning environments
- [ ] Members of a federally recognized American Indian and Alaska Native tribe
- [x] **None of the Above**

Populations with Special Considerations Section Complete

Protocol Progress:
● **INITIAL SETUP**
● **BACKGROUND, RATIONALE & GOALS**
● **RESEARCH PLAN**
● **CONSENT PLAN**
● **RISKS, PRIVACY & CONFIDENTIALITY**
● **POPULATIONS WITH SPECIAL CONSIDERATIONS**
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Study Funding

1. * **Have you applied for funding:**
   - (●) **Yes**
   - ( ) No

2. **Is this study already funded:**
   - (●) **Yes**
   - ( ) No

3. * **Select all funding sources for this study (pending or awarded):**
   - [ ] Industry
   - [x] **Direct Federal**
   - [ ] Indirect Federal
   - [ ] State/Local Government
   - [ ] Non-Profit - Sponsored Project
   - [ ] Non-Profit - Gift
   - [ ] Internal Grant
   - [ ] Investigator/Departmental Funds
   - [ ] None
   - [ ] Other

4. * **In addition to providing funding support, what is the funding source's role in this study? Select all that apply:**
   - [x] **Solely providing funding support**
   - [ ] Providing resources (e.g. study drug, device)
   - [ ] Providing guidance to the researcher but does NOT make decisions about study design
   - [ ] Study design/Creation of the study protocol
   - [ ] Collaborator in the research (helps design and/or conduct the study) [list the funder as a site on the Types of Sites page]
   - [ ] Data or sample analysis regardless of identifiability

5. **Select all related funding proposals and contracts that have been submitted through the Division of Sponsored Programs (DSP):**

RAMS-SPOT ID# (FP/PT/PD#)	Direct Sponsor	PI	Title	Status	Start	End
FP00006477	National Institutes of Health	Thomas Eissenberg	Center for the Study of Tobacco Products	Funded		

6. **If the following conditions are ALL met, provide the index code where the HRPP will charge Single IRB (sIRB) fees associated with this review:**
   1. The study is externally funded (fees do not apply if the study is not funded), AND
   2. Multiple sites are executing the same research protocol (i.e. multicenter research), AND
   3. VCU IRB will provide IRB review on behalf of one or more non-VCU sites
   N/A

7. * **Does the funder require the IRB to review this proposal for grant congruence?**

- ○ Yes
- ● **No**

Types of Sites

VCU Site Information

1. * **Select all VCU sites that will be utilized in this study:**
   - ☐ Children's Hospital of Richmond at VCU
   - ☐ Clinical Research Services Unit (CRSU)
   - ☐ Massey Cancer Center
   - ☐ VCU Health Community Memorial Hospital
   - ☐ VCU Health Tappahannock Hospital
   - ☐ VCU Medical Center
   - ☐ Other VCU Health Location
   - ☐ VCU Monroe Park Campus
   - ☐ VCU Qatar
   - ☑ **Other VCU Site**

Non-VCU Site Information

Non-VCU sites should be selected whenever any of the following situations apply:
a) Non-VCU sites that will be collaborating on a VCU-led study (i.e. involved in conducting the research, including being involved in the study interpretation or analysis of data and/or authorship of presentations or manuscripts related to the research.)
b) Non-VCU sites that will be deferring to the VCU IRB for IRB review
c) Non-VCU sites where VCU investigators will be overseeing study interventions or interactions
d) Non-VCU sites/locations where VCU investigators will conduct study activities

2. * **Select any of the following non-VCU sites utilized in this study:**
   - ☐ McGuire VAMC
   - ☐ Foreign Sites
   - ☐ Other Non-VCU Sites
   - ☑ **No Non-VCU Sites**

3. * **Is this a multi-center study being led by VCU?**
   - ○ Yes ● **No**

4. **For Non-VCU Sites: For each site or institution listed as "Site Engaged -- Requests to Rely on VCU IRB Review," upload:**

   - Completed Local Context Form for Relying on VCU's IRB
   - Site specific informed consent form(s) and HIPAA authorization(s), if applicable

   For Foreign Sites: For each Cultural Consultant upload a CV/Biosketch that includes a clear description of cultural expertise:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Informed Consent	P3 TASTE_Informed Consent_CLEAN_1.29.2024.pdf	0.15	2/20/2024 10:22 AM	Rabia Imran	Consent/Assent/Information Sheet	Yes
View	Consent - Tool	P3TASTE_Consent_Presentation_1.29.2024.pptx	0.06	1/30/2024 1:34 PM	Rabia Imran	Consent/Assent/Information Sheet	Yes
View	Social Media Plan	P3-TASTE Social Media Plan_10.2.2023.docx	0.01	10/2/2023 3:29 PM	Caroline Cobb Amey	Recruitment/Advertising	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Social Media and Craigslist Ads	P3-TASTE_facebook and craiglist ads_10.2.2023.docx	0.01	10/2/2023 3:29 PM	Caroline Cobb Amey	Recruitment/Advertising	Yes
View	Substance Use Resources Handout	CSTP Substance Use Resources_8.11.2023.docx	0.01	8/11/2023 5:11 PM	Caroline Cobb Amey	Other	Yes
View	Subjective Measures	P3-TASTE-Session Subjective Measures_CLEAN_08.09.2023.doc	0.03	8/11/2023 5:10 PM	Rabia Imran	Research Measure	Yes
View	P3 TASTE Advertisement for CSTP Website	P3 TASTE - CSTP Website Study Description_CLEAN_08.08.2023.docx	0.05	8/11/2023 5:09 PM	Rabia Imran	Recruitment/Advertising	Yes
View	Presession Symptom Questions	P3-Presession symptom Checklist-CLEAN_08.09.2023.docx	0.05	8/11/2023 5:08 PM	Rabia Imran	Research Measure	Yes
View	Baseline Self Report Physio Measures	P3-TASTE_Baseline forms All_CLEAN_8.11.2023.docx	0.06	8/11/2023 5:07 PM	Rabia Imran	Research Measure	Yes
View	Text, Email, Call Scripts	P3-TASTE_Phone_e-mail_text scripts_08.09.2023_CLEAN.docx	0.10	8/11/2023 5:06 PM	Rabia Imran	Study reminders/communications	Yes
View	Referral Program Card Template	P3_Referral program card_06.02.2023_CLEAN.docx	0.03	6/13/2023 1:48 PM	Rabia Imran	Recruitment/Advertising	Yes
View	COVID-19 Questions	COVID_Questions_P3_no longer using.docx	0.02	6/13/2023 1:35 PM	Rabia Imran	Other	Yes
View	P3 Taste_ETM	P3-TASTE_Measures_ETM__no longer using.docx	0.04	6/13/2023 1:35 PM	Rabia Imran	Research Measure	Yes
View	Tobacco Cessation Resources Handout	Cessation_handout_RI_04.29.2021.pdf	0.01	2/1/2023 3:32 PM	Caroline Cobb Amey	Other	Yes
View	U54 Grant Application Without Budget	U54 Grant Application BUDGET PAGES DELETED FOR IRB.pdf	0.01	10/28/2022 2:17 PM	Rabia Imran	Funding Proposal	Not Applicable
View	CP-DPT & DPT	P3-TASTE Drug Purchase Tasks_9.2.2022.docx	0.01	10/28/2022 2:03 PM	Rabia Imran	Research Measure	Yes
View	CP-DPT & DPT - Tool	DPT_CDPT presentation_10.28.2022.pptx	0.01	10/28/2022 2:03 PM	Rabia Imran	Research Measure	Yes
View	Subjective Measures - Tool	Subjective Measures presentation_10.28.2022.pptx	0.01	10/28/2022 2:00 PM	Rabia Imran	Research Measure	Yes
View	Barnes Biosketch	P3 Barnes biosketch 06.22.17.FINAL.docx	0.01	10/28/2022 1:55 PM	Rabia Imran	CV/Biosketch	Not Applicable
View	Lipato Biosketch	Lipato Biosketch.pdf	0.01	10/28/2022 1:54 PM	Rabia Imran	CV/Biosketch	Yes
View	Caroline Cobb (Amey) CV	CV_Cobb_August 2022.docx	0.01	10/28/2022 1:54 PM	Rabia Imran	CV/Biosketch	Yes
View	Baseline Discounting Task - MDT	P3_TASTE_Discounting Task_11.7.2018.pdf	0.01	10/28/2022 1:54 PM	Rabia Imran	Research Measure	Yes
View	U54 Project 3 Grant Docs	U54_Project 3 only docs.pdf	0.01	10/28/2022 1:53 PM	Rabia Imran	Funding Proposal	Not Applicable
View	CSTP Parking Map	CSTP Parking Map.docx	0.01	10/28/2022 1:52 PM	Rabia Imran	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Criticare HR/BP Manual	Criticare_Vitalcare_506N3_-_Service_manual.pdf	0.01	10/28/2022 1:52 PM	Rabia Imran	Other	Not Applicable
View	Expired Air CO Manual	CO Monitor Manual.pdf	0.01	10/28/2022 1:51 PM	Rabia Imran	Other	Not Applicable
View	Information about Blood Pressure	BP results P3 flux 8.22.2022.docx	0.01	10/28/2022 1:51 PM	Rabia Imran	Study reminders/communications	Yes
View	CSTP Registry Consent and Survey	CSTP Registry Consent Form and Questions.pdf	0.01	10/19/2022 3:27 PM	Caroline Cobb Amey	Other	Not Applicable

Personnel

1. * **List all VCU/VCUHS personnel who are key study personnel.**

Key personnel are defined as including:

- **Conflict of interest investigators, including**
- **the PI**
- **the Lead Student/Trainee Investigator,**
- **medically/Psychologically responsible investigator(s)**
- **FDA Form 1572 investigators, and**
- **Other personnel whose roles are essential to the conduct of the research.**

Note: Individuals who are not key personnel are not required to be listed here, but PIs still bear the responsibility to document the delegation of responsibilities in the study records.

PIs may elect to use the Study Roster activity button in RAMS-IRB (available after approval) as an alternative way to document study staff involvement and delegation of responsibilities. Personnel changes made to the non-key personnel listed in the separate Study Roster activity do not require an amendment.

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
View	Caroline Cobb Amey	Principal Investigator		Data Analysis Project Coordination Participant Consent Data Collection - Lab Data Management Participant Identification Data Entry Study Design Data Coding Participant Recruitment Data Collection - Interviews/Surveys		Experience - Research Education and/or Professional Preparation		yes
View	Andrew Barnes	Co/Sub-Investigator		Data Analysis Project Coordination Participant Consent Data Collection - Lab Data Management Participant Identification Data Entry Study Design Data Coding Participant Recruitment Data Collection - Interviews/Surveys		Experience - Research Education and/or Professional Preparation		yes

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
View	Alison Breland	Co/Sub-Investigator		Data Analysis Project Coordination Participant Consent Data Collection - Lab Participant Identification Data Entry Study Design Data Coding Participant Recruitment Data Collection - Interviews/Surveys		Experience - Research Education and/or Professional Preparation		yes
View	Thomas Eissenberg	Co/Sub-Investigator		Data Analysis Data Management Participant Identification Study Design		Experience - Research Education and/or Professional Preparation		yes
View	Thokozeni Lipato	Medical or Psychological Responsible Investigator		Data Management Participant Identification Data Entry Clinical Services		Experience - Research Experience - Clinical Education and/or Professional Preparation		yes
View	Nicoleta Gaitan	Research Nurse		Project Coordination Other Participant Recruitment Clinical Services	Provide medical safety supervision/consultation	Experience - Research Experience - Clinical Education and/or Professional Preparation		no
View	Rabia Imran	Research Assistant		Data Analysis Project Coordination Data Collection - Direct Observation Participant Consent Data Collection - Lab Data Management Data Entry Data Coding Participant Recruitment Data Collection - Interviews/Surveys		Experience - Research Experience - Related Skills Education and/or Professional Preparation		no
View	Augustus White	Research Assistant		Data Analysis		Experience - Research		no

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
		Trainee/Student(working on project)		Data Collection - Direct Observation Participant Consent Data Collection - Lab Data Management Data Entry Data Coding Participant Recruitment Data Collection - Interviews/Surveys		Education and/or Professional Preparation Student		
View	Rose Bono	Research Assistant		Data Analysis Data Management Data Coding		Experience - Research Education and/or Professional Preparation		no
View	Mary Bridgman	Research Assistant		Data Analysis Project Coordination Data Collection - Direct Observation Participant Consent Data Collection - Lab Data Management Data Entry Data Coding Participant Recruitment Data Collection - Interviews/Surveys		Experience - Research Experience - Related Skills Education and/or Professional Preparation		no
View	Melody Falter	Research Assistant		Data Analysis Project Coordination Participant Consent Data Collection - Lab Data Management Participant Identification Data Entry Data Coding Participant Recruitment Data Collection - Interviews/Surveys		Experience - Research Experience - Related Skills Education and/or Professional Preparation		no
View	Carrico	Research Assistant Trainee/Student(working on project)		Data Analysis Participant Consent Data Collection - Lab		Experience - Research Experience - Related Skills		no

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
				Data Management Participant Identification Data Entry Data Coding Participant Recruitment Data Collection - Interviews/Surveys		Education and/or Professional Preparation Student		
View	Elizabeth Ogunleye	Trainee/Student(working on project)		Data Analysis Project Coordination Data Collection - Direct Observation Participant Consent Data Collection - Lab Data Management Participant Identification Data Entry Data Coding Participant Recruitment Data Collection - Interviews/Surveys		Experience - Research Experience - Related Skills Education and/or Professional Preparation Student		no

2. **Identify all independent investigators and key personnel at non-VCU sites who will be engaged in this study AND who DO NOT have IRB approval for this study from their own institution.**

Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator

There are no items to display

3. If independent investigators or community engaged investigators are listed above,**describe the human subjects training these individuals will complete and the process that will be used to ensure that all persons assisting with the research are adequately informed about the protocol and their research related duties and functions:**
This study will be conducted in Dr. Eissenberg's and Breland's Center for the Study of Tobacco Products. In over 15 years, the CSTP has conducted numerous IRB-approved studies involving cigarette smokers and e-cigarette users. All laboratory personnel are experienced, well-trained and aware of their protocol-related responsibilities. Additionally, most lab personnel, including the Co-PIs have offices on the same floor in the same building and communicate daily in-person regarding all study-related issues. Lab meetings are held bi-monthly in order to communicate the status of specific studies and any issues related to ongoing studies. Thurs, communication may occur as often as every day, either in person or via email.

Communication with between laboratory staff and the Co-PIs/Medical Monitor occurs as soon as possible during and/or after any adverse event occurs. The Co-PIs and Medical Monitor are available by mobile phone, office phone, and email. These numbers are posted centrally in the laboratory.

4. * **Upload a CV or Biosketch for the PI, Medically/Psychologically Responsible Investigators and the lead Student/Trainee Investigators. Do not upload CVs or Biosketches for other individuals.**

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Informed Consent	P3 TASTE_Informed Consent_CLEAN_1.29.2024.pdf	0.15	2/20/2024 10:22 AM	Rabia Imran	Consent/Assent/Information Sheet	Yes
View	Consent - Tool	P3TASTE_Consent_Presentation_1.29.2024.pptx	0.06	1/30/2024 1:34 PM	Rabia Imran	Consent/Assent/Information Sheet	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Social Media Plan	P3-TASTE Social Media Plan_10.2.2023.docx	0.01	10/2/2023 3:29 PM	Caroline Cobb Amey	Recruitment/Advertising	Yes
View	Social Media and Craigslist Ads	P3-TASTE_facebook and craiglist ads_10.2.2023.docx	0.01	10/2/2023 3:29 PM	Caroline Cobb Amey	Recruitment/Advertising	Yes
View	Substance Use Resources Handout	CSTP Substance Use Resources_8.11.2023.docx	0.01	8/11/2023 5:11 PM	Caroline Cobb Amey	Other	Yes
View	Subjective Measures	P3-TASTE-Session Subjective Measures_CLEAN_08.09.2023.doc	0.03	8/11/2023 5:10 PM	Rabia Imran	Research Measure	Yes
View	P3 TASTE Advertisement for CSTP Website	P3 TASTE - CSTP Website Study Description_CLEAN_08.08.2023.docx	0.05	8/11/2023 5:09 PM	Rabia Imran	Recruitment/Advertising	Yes
View	Presession Symptom Questions	P3-Presession symptom Checklist-CLEAN_08.09.2023.docx	0.05	8/11/2023 5:08 PM	Rabia Imran	Research Measure	Yes
View	Baseline Self Report Physio Measures	P3-TASTE_Baseline forms All_CLEAN_8.11.2023.docx	0.06	8/11/2023 5:07 PM	Rabia Imran	Research Measure	Yes
View	Text, Email, Call Scripts	P3-TASTE_Phone_e-mail_text scripts_08.09.2023_CLEAN.docx	0.10	8/11/2023 5:06 PM	Rabia Imran	Study reminders/communications	Yes
View	Referral Program Card Template	P3_Referral program card_06.02.2023_CLEAN.docx	0.03	6/13/2023 1:48 PM	Rabia Imran	Recruitment/Advertising	Yes
View	COVID-19 Questions	COVID_Questions_P3_no longer using.docx	0.02	6/13/2023 1:35 PM	Rabia Imran	Other	Yes
View	P3 Taste_ETM	P3-TASTE_Measures_ETM__no longer using.docx	0.04	6/13/2023 1:35 PM	Rabia Imran	Research Measure	Yes
View	Tobacco Cessation Resources Handout	Cessation_handout_RI_04.29.2021.pdf	0.01	2/1/2023 3:32 PM	Caroline Cobb Amey	Other	Yes
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View	Caroline Cobb (Amey) CV	CV_Cobb_August 2022.docx	0.01	10/28/2022 1:54 PM	Rabia Imran	CV/Biosketch	Yes
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View	Criticare HR/BP Manual	Criticare_Vitalcare_506N3_-_Service_manual.pdf	0.01	10/28/2022 1:52 PM	Rabia Imran	Other	Not Applicable
View	Expired Air CO Manual	CO Monitor Manual.pdf	0.01	10/28/2022 1:51 PM	Rabia Imran	Other	Not Applicable
View	Information about Blood Pressure	BP results P3 flux 8.22.2022.docx	0.01	10/28/2022 1:51 PM	Rabia Imran	Study reminders/communications	Yes
View	CSTP Registry Consent and Survey	CSTP Registry Consent Form and Questions.pdf	0.01	10/19/2022 3:27 PM	Caroline Cobb Amey	Other	Not Applicable

HM20025464 - Caroline Cobb Amey
Effects of Electronic Cigarette Flavors on Abuse Liability in Smokers (P3-Taste)

Conflict of Interest

The PI should ask the questions on this page of all research personnel who are engaged in the research, including subrecipient investigators and personnel.

1. * **To the best of your knowledge, do you (as PI) or any other engaged individual have a financial interest related to this study?**
   Financial interest include utilizing your licensed intellectual property in the study; serving as a paid consultant, or advisory board member, or officer/director with a related entity; and equity or business ownership in a company that is related to this project
   ● **Yes** ○ No

2. * **If Yes, provide:**
   - Name(s) of engaged individual(s) with a related financial interest
   - Brief description of financial interest

   Any individual named here should be designated as a 'COI Investigator' on the Personnel page, even if they were not initially designated as a 'COI Investigator', and complete a Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS). Ensure that all designated 'COI investigators,' including the PI, and any others listed here with related interests are up to date in the AIRS (https://airs.research.vcu.edu)
   Dr. Eissenberg is a paid consultant in litigation against the tobacco industry and the electronic cigarette industry.

3. * **To the best of your knowledge, do you (as PI) or any other engaged individual have a non-financial interest related to this study?**
   Non-financial Interests could include such things as:
   - utilizing your unlicensed intellectual property in the study,
   - serving as an unpaid advisory board member or officer/director with a related entity, and
   - equity or business ownership in a company that has yet to make a profit and is related to this project
   - conflict of time/effort,
   - personal and professional relationships/affiliations,
   - intellectual passions or personal beliefs
   - other factors that could create bias in the study
   ● **Yes** ○ No

4. * **Describe any If Yes, provide:**
   - Name(s) of the engaged individual(s) with a related non-financial interest
   - Brief description of the non-financial interest

   Any individual named here should also complete a Financial Interest Report (FIR) in the Activity and Interest Report System (AIRS), even if they were not initially designated as a 'COI Investigator.' Ensure that all designated 'COI investigators,' including the PI, and any others listed here with related interests are up to date in the AIRS (https://airs.research.vcu.edu)
   Dr. Eissenberg is named on a patent application for a device that measures the puffing behavior or electronic cigarette users.

5. **Describe any institutional conflict of interest that you or any member of the research team are aware of that pertains to this research:**

   An institutional conflict of interest is a situation in which financial interests of the University or University leadership may affect research activities at VCU.
   N/A

Other VCU Requirements

This page asks questions on behalf of other ancillary offices, committees and departments at VCU regarding institutional requirements that could apply to this research. In some cases, these requirements could also impact the consent process or other aspects of the IRB's review.

Based upon answers provided earlier in this form, certain ancillary sections below may not have questions displayed if those requirements are not applicable to this study.

1. Cost Coverage Analysis

Information on coverage analysis requirements and processes can be found through VCU's Clinical Research Compliance Program at https://research.vcu.edu/human-research/clinical-research/vcu-clinical-research-coverage-analysis/

1. * **VCU requires that all clinical research studies be evaluated to determine if a Coverage Analysis is required. Has your study been evaluated by an institutionally designated Coverage Analysis Specialist?**
   - (●) **Yes**
   - ( ) No
   - ( ) Not Applicable

2. ClinicalTrials.gov Program & OnCore

For guidance, see https://cctr.vcu.edu/support/consultation/clinical-trials-gov/ or email CCTRCTGOV@vcu.edu

1. * **Is this a Clinical Trial?**
   (●) **Yes** ( ) No

2. * **ThePI acknowledges awareness of the following requirements for posting clinical trial consent forms:**

   - Each clinical trial under the 2018 Common Rule that is conducted or supported by a Federal department or agency must post one IRB-approved consent form that was used to enroll subjects on a publicly available Federal website [45 CFR 46.116(h)].
   - When engaged in multi-site research, the VCU PI is responsible for confirming with the lead site who is responsible for posting the informed consent form.
   - When VCU is the lead site, the VCU PI is responsible for posting the informed consent form (unless the federal department or agency will post it).

   (●) **Yes** ( ) No

3. Community Engagement

For more information, see https://community.vcu.edu/

1. * **Is this a community engaged research study? (See help text for definitions)**
   - ( ) Yes
   - (●) **No**

4. Family Educational Rights and Privacy Act (FERPA) Requirements

For guidance, see https://rar.vcu.edu/records/family-educational-rights-and-privacy-act/

1. * **Does this study involve obtaining information from VCU students' educational records (see help text)?**
   - ( ) Yes
   - (●) **No**

5. Research Data Privacy Requirements

Contact the VCU Research Data Privacy Office with questions: https://research.vcu.edu/integrity-and-compliance/compliance/research-data-privacy/

1. * **Does this study involve the VCU site (regardless of the IRB of record), or any sites under the VCU IRB"s oversight, obtaining data in, or from, a foreign country?**
   ○ Yes ● **No**

6. Information Security
For guidance, see https://ts.vcu.edu/askit/essential-computing/information-security/

1. * **Using the VCU Data Classification Tool, please determine the appropriate data classification category for the data that will be collected or used in this research.**

   Note: if the data falls into Category 1, a data security management plan is required by University Information Security Office.

   See help text for information on accessing the VCU Data Classification Tool, and for information on creating a data security management plan at https://dms.vcu.edu**.**
   ● **Category 1: all data that require breach notifications in the event of improper release, including personally identifiable information covered by HIPAA and Commonwealth of Virginia regulations.**
   ○ Category 2: all proprietary data that if improperly released has the potential to cause harm to the institution, its mission or its reputation that do not require breach notifications.

2. * **I confirm use of the VCU Data Classification Tool at** https://go.vcu.edu/dataclassification **in determining the data classification category selected in Question 1:**
   ● **Yes**
   ○ No

3. * **The PI is aware that if the study's data is classified as Category 1, a Data Management Plan must be submitted to and approved by VCU Information Security prior to IRB approval. See** https://ts.vcu.edu/askit/essential-computing/information-security/data-management-system/
   ● **Yes** ○ No

4. * **I confirm that any use of external technology has been submitted to Information Security in the study's Data Management Plan. If this study uses any technology platforms, apps, services, etc. that are maintained external to VCU or hosted by another institution and are NOT currently listed in the DMS system as an approved service for the storage, processing, or transmission of VCU data, I am required to have VCU Information Security conduct a security review of that technology. I may contact infosec@vcu.edu with questions.**

   I also confirm that if the study involves use of external technology and VCUHS HIPAA data, I must also seek security review from the VCUHS Data Governance group (contact Mary Harmon at mary.harmon@vcuhealth.org):
   ● **Yes**
   ○ No
   ○ N/A - not using external technology

7. Massey Cancer Center Protocol Review and Monitoring Committee (PRMC)
For guidance, see https://www.masseycancercenter.org/research/~/link.aspx?_id=ee49e95faa8b44d09b6e89d8e3b48b57&_z=z

1. * **Does this study involve any of the following?**
   - Research involving patients with cancer, their families or their health care providers
   - Research involving cancer screening, diagnosis or prevention
   - Secondary data collected from cancer patients or their medical records
   - Cancer-related surveys (e.g., attitudes about risk, prevention and treatment) of the general population
   ○ Yes
   ● **No**

8. VCU ONETRAC Protocol Review Oversight Committees (PROCs) For guidance, see https://onetrac.vcu.edu/

1. * **Does this study involve research with any of the following?**

   - VCU Health System patients

   - VCU Health System facilities

   - VCU Health System data

   ○ Yes

   ● **No**

9. VCU Health Department of Patient Centered Services

1. * **Does your study involve a satisfaction survey administered to VCUHS patients (*See Help Text):**

   ○ Yes

   ○ No

   ● **Not Applicable**

10. VCU Faculty-Held IND or IDE

For guidance, see **https://research.vcu.edu/human-research/regulatory-affairs/**.

Questions related to if you need an IND or IDE for your study should be emailed to: indide@vcu.edu. Please submit a copy of your FDA
submission prior to submitting to the FDA to https://redcap.vcu.edu/surveys/?s=NR7K7LR4JW.

11. VCU Health System locations

1. * **Will research activities occur in patient care areas of the VCU Health System (including at CHoR, Community Memorial Hospital, Tappahannock Hospital, VCU Medical Center and Massey Cancer Center)?**

   ○ Yes

   ● **No**

12. VCUHS Department of Pathology

Learn more about requesting and establishing an account with Pathology here: See https://pathology.vcu.edu/research-services/

1. * **I am aware that I may need to establish a research account with VCUHS Department of Pathology for specimen processing:**

   ● **Yes**

   ○ No

2. * **I have contacted VCUHS Department of Pathology to determine feasibility if my study involves the following:**
   - Storage of Microbiology isolates
   - New instrumentation provided by clinical trial/study sponsor, or
   - Non-routine specimen processing (examples include but aren't limited to the following: addition of reagents to samples/aliquots, buffy coat processing, DNA sample processing)

   ○ Yes

   ○ No

   ● **N/A - my study does not involve any of the listed processes.**

3. * **If my study involves specimen retrieval from the Pathology laboratory, I have established a process with Pathology to deidentify and retrieve specimens.**

   ○ Yes

   ○ No

   ● **N/A - my study won't involve specimen retrieval from Pathology**

13. VCU Institutional Biosafety Committee (IBC)
To contact the Biosafety Office see their website at: https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/

1. * **Does this project involve any of the following hazardous biological agents ("biohazardous agents") that have NOT been FDA approved? These may include, but are not limited to, any of the following. If you are unsure, please contact the Biosafety Office:**

- Any functional recombinant viruses (especially viruses that may integrate into the patients' genome).

- Expression or administration of biological toxins.

- Live pathogenic or potentially pathogenic organisms of plants or animals (bacteria, fungi, wild-type viruses, parasites, etc.), that are, or potentially may be, in experimental products.

- Introduction or expression of rDNA or synthetic nucleic acids

- Use of a product (e.g., monoclonal antibodies, recombinant cytokines) produced from virally infected mammalian cells.

- Use of a product (purified growth factors, cytokines) produced from mammals or their cells.

○ Yes ● **No**

14. VCU Radiation Safety Committee (RSC)
To contact the Radiation Safety Section see their website at: https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/

1. * **Does this study involve radiation exposure and/or scans involving radiation (e.g.: PET, MRA, CT, DXA, nuclear medicine, etc.)?**

○ Yes

● **No**

15. VCU Scientific Review Committee (SRC)
For guidance, see https://cctr.vcu.edu/support/consultation/scientific-review-committee/

1. * **Has this human subjects protocol (not the grant application) already been reviewed by the funder of a sponsored project (e.g. a federal, state or non-profit funding sponsor)?**

○ Yes

● **No**

Based upon your responses, this study will be routed to the VCU Scientific Review Committee (SRC) when it is submitted. After SRC review is completed, the IRB will receive the study.

16. Upload any documents requested in the questions above:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Informed Consent	P3 TASTE_Informed Consent_CLEAN_1.29.2024.pdf	0.15	2/20/2024 10:22 AM	Rabia Imran	Consent/Assent/Information Sheet	Yes
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View	Social Media Plan	P3-TASTE Social Media Plan_10.2.2023.docx	0.01	10/2/2023 3:29 PM	Caroline Cobb Amey	Recruitment/Advertising	Yes
View	Social Media and Craigslist Ads	P3-TASTE_facebook and craiglist ads_10.2.2023.docx	0.01	10/2/2023 3:29 PM	Caroline Cobb Amey	Recruitment/Advertising	Yes
View	Substance Use	CSTP Substance Use Resources_8.11.2023.docx	0.01	8/11/2023 5:11 PM	Caroline Cobb Amey	Other	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Resources Handout						
View	Subjective Measures	P3-TASTE-Session Subjective Measures_CLEAN_08.09.2023.doc	0.03	8/11/2023 5:10 PM	Rabia Imran	Research Measure	Yes
View	P3 TASTE Advertisement for CSTP Website	P3 TASTE - CSTP Website Study Description_CLEAN_08.08.2023.docx	0.05	8/11/2023 5:09 PM	Rabia Imran	Recruitment/Advertising	Yes
View	Presession Symptom Questions	P3-Presession symptom Checklist-CLEAN_08.09.2023.docx	0.05	8/11/2023 5:08 PM	Rabia Imran	Research Measure	Yes
View	Baseline Self Report Physio Measures	P3-TASTE_Baseline forms All_CLEAN_8.11.2023.docx	0.06	8/11/2023 5:07 PM	Rabia Imran	Research Measure	Yes
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View	Tobacco Cessation Resources Handout	Cessation_handout_RI_04.29.2021.pdf	0.01	2/1/2023 3:32 PM	Caroline Cobb Amey	Other	Yes
View	U54 Grant Application Without Budget	U54 Grant Application BUDGET PAGES DELETED FOR IRB.pdf	0.01	10/28/2022 2:17 PM	Rabia Imran	Funding Proposal	Not Applicable
View	CP-DPT & DPT	P3-TASTE Drug Purchase Tasks_9.2.2022.docx	0.01	10/28/2022 2:03 PM	Rabia Imran	Research Measure	Yes
View	CP-DPT & DPT - Tool	DPT_CDPT presentation_10.28.2022.pptx	0.01	10/28/2022 2:03 PM	Rabia Imran	Research Measure	Yes
View	Subjective Measures - Tool	Subjective Measures presentation_10.28.2022.pptx	0.01	10/28/2022 2:00 PM	Rabia Imran	Research Measure	Yes
View	Barnes Biosketch	P3 Barnes biosketch 06.22.17.FINAL.docx	0.01	10/28/2022 1:55 PM	Rabia Imran	CV/Biosketch	Not Applicable
View	Lipato Biosketch	Lipato Biosketch.pdf	0.01	10/28/2022 1:54 PM	Rabia Imran	CV/Biosketch	Yes
View	Caroline Cobb (Amey) CV	CV_Cobb_August 2022.docx	0.01	10/28/2022 1:54 PM	Rabia Imran	CV/Biosketch	Yes
View	Baseline Discounting Task - MDT	P3_TASTE_Discounting Task_11.7.2018.pdf	0.01	10/28/2022 1:54 PM	Rabia Imran	Research Measure	Yes
View	U54 Project 3 Grant Docs	U54_Project 3 only docs.pdf	0.01	10/28/2022 1:53 PM	Rabia Imran	Funding Proposal	Not Applicable
View	CSTP Parking Map	CSTP Parking Map.docx	0.01	10/28/2022 1:52 PM	Rabia Imran	Other	Not Applicable
View	Criticare HR/BP Manual	Criticare_Vitalcare_506N3_-_Service_manual.pdf	0.01	10/28/2022 1:52 PM	Rabia Imran	Other	Not Applicable
View	Expired Air CO Manual	CO Monitor Manual.pdf	0.01	10/28/2022 1:51 PM	Rabia Imran	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Information about Blood Pressure	BP results P3 flux 8.22.2022.docx	0.01	10/28/2022 1:51 PM	Rabia Imran	Study reminders/communications	Yes
View	CSTP Registry Consent and Survey	CSTP Registry Consent Form and Questions.pdf	0.01	10/19/2022 3:27 PM	Caroline Cobb Amey	Other	Not Applicable

HIPAA

In order for VCUHS to meet HIPAA regulations regarding accounting of disclosures, data retention, and data destruction requirements for PHI data obtained without patient authorization, members of the study team (including principal investigators) are directed to consult with VCU Informatics to obtain any VCUHS data. This does not include obtaining data for which the study team has patient authorization. [VCU Health System Authority and Affiliates Policy COMP-014]

For data requests, including preparatory to research and research with decedents, submit a request for the desired PHI, or for a consultation on alternate methods to obtain the data, at https://informatics.vcu.edu.

HIPAA Privacy Board Requirements

For guidance, see https://www.vcuhealth.org/our-story/who-we-are/compliance-services/compliance-services

1. * **Select the source of the Individually Identifiable Health Information. See help text for definitions.**
   - ☐ PHI associated with or derived from (i.e. obtained from or entered into) VCU Health medical records or VCU Dental Care records
   - ☑ **Research Health Information (RHI) created or received by a study and kept solely in study records (e.g. self reported or the result of research tests and not entered into health records)**
   - ☐ PHI associated with or derived from (i.e. obtained from or entered into) a non-VCU HIPAA covered entity's health records

Institutional Requirements Complete

Protocol Progress:
- **INITIAL SETUP**
- **BACKGROUND, RATIONALE & GOALS**
- **RESEARCH PLAN**
- **CONSENT PLAN**
- **RISKS, PRIVACY & CONFIDENTIALITY**
- **POPULATIONS WITH SPECIAL CONSIDERATIONS**
- **INSTITUTIONAL REQUIREMENTS**

⑧ DOCUMENTS

Click Continue below to go to the next section

HM20025464 - Caroline Cobb Amey
Effects of Electronic Cigarette Flavors on Abuse Liability in Smokers (P3-Taste)

Documents

1. **Upload any documents that the VCU IRB will need to conduct a review of this submission:**
   A list of potential documents is given in the help text.

NOTE: The delete function should only be used if an incorrect document is uploaded or added to the system AND that document has not been reviewed and approved by the IRB. Do NOT delete documents that the IRB previously reviewed and approved.

Once you have uploaded a document to RAMS-IRB, any changes to that document (i.e. different versions of the same document) should be added to the IRB submission by using the Update button. To provide updated documents, follow these steps:

- Click the Update button located to the left of the document to be updated.
- In the Add Document window, click the Choose File or Browse button, select the file you are adding, and click on the Open button.
- Click OK to close the Add Document window, and the system will upload the revised document. RAMS-IRB will automatically provide a version number for the document.

To access previous versions of a document in RAMS-IRB you must use the History link associated with the document.

- Click the View or Update button located to the left of the document you wish to access.
- In the Add/View Document window, click the "History" hyperlink located to the right of the file name.
- A separate window will open that shows all versions of the document that have been added to RAMS-IRB. Click on any file name to download and view the document.

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Informed Consent	P3 TASTE_Informed Consent_CLEAN_1.29.2024.pdf	0.15	2/20/2024 10:22 AM	Rabia Imran	Consent/Assent/Information Sheet	Yes
View	Consent - Tool	P3TASTE_Consent_Presentation_1.29.2024.pptx	0.06	1/30/2024 1:34 PM	Rabia Imran	Consent/Assent/Information Sheet	Yes
View	Social Media Plan	P3-TASTE Social Media Plan_10.2.2023.docx	0.01	10/2/2023 3:29 PM	Caroline Cobb Amey	Recruitment/Advertising	Yes
View	Social Media and Craigslist Ads	P3-TASTE_facebook and craiglist ads_10.2.2023.docx	0.01	10/2/2023 3:29 PM	Caroline Cobb Amey	Recruitment/Advertising	Yes
View	Substance Use Resources Handout	CSTP Substance Use Resources_8.11.2023.docx	0.01	8/11/2023 5:11 PM	Caroline Cobb Amey	Other	Yes
View	Subjective Measures	P3-TASTE-Session Subjective Measures_CLEAN_08.09.2023.doc	0.03	8/11/2023 5:10 PM	Rabia Imran	Research Measure	Yes
View	P3 TASTE Advertisement for CSTP Website	P3 TASTE - CSTP Website Study Description_CLEAN_08.08.2023.docx	0.05	8/11/2023 5:09 PM	Rabia Imran	Recruitment/Advertising	Yes
View	Presession Symptom Questions	P3-Presession symptom Checklist-CLEAN_08.09.2023.docx	0.05	8/11/2023 5:08 PM	Rabia Imran	Research Measure	Yes
View	Baseline Self Report Physio Measures	P3-TASTE_Baseline forms All_CLEAN_8.11.2023.docx	0.06	8/11/2023 5:07 PM	Rabia Imran	Research Measure	Yes
View	Text, Email, Call Scripts	P3-TASTE_Phone_e-mail_text scripts_08.09.2023_CLEAN.docx	0.10	8/11/2023 5:06 PM	Rabia Imran	Study reminders/communications	Yes
View	Referral Program Card Template	P3_Referral program card_06.02.2023_CLEAN.docx	0.03	6/13/2023 1:48 PM	Rabia Imran	Recruitment/Advertising	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	COVID-19 Questions	COVID_Questions_P3_no longer using.docx	0.02	6/13/2023 1:35 PM	Rabia Imran	Other	Yes
View	P3 Taste_ETM	P3-TASTE_Measures_ETM__no longer using.docx	0.04	6/13/2023 1:35 PM	Rabia Imran	Research Measure	Yes
View	Tobacco Cessation Resources Handout	Cessation_handout_RI_04.29.2021.pdf	0.01	2/1/2023 3:32 PM	Caroline Cobb Amey	Other	Yes
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HM20025464 - Caroline Cobb Amey
Effects of Electronic Cigarette Flavors on Abuse Liability in Smokers (P3-Taste)

Documents Complete

Protocol Progress:
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- **POPULATIONS WITH SPECIAL CONSIDERATIONS**
- **INSTITUTIONAL REQUIREMENTS**
- **DOCUMENTS**

End of Application

Click Continue below to exit and submit this project

Bio-Medical Project Drugs

1. * **Drug:**
   NJOY Ace 2.4% nicotine - Menthol (flavor)

2. * **Manufacturer:**
   NJOY LLC

3. * **Select all types that apply:**

- [ ] FDA Approved and being used as approved
- [ ] Marketed Drug/Biologic Exempt from IND
- [ ] Investigational Drug/Biologic/Supplement used as drug
- [ ] Supplement
- [ ] Over the Counter Medication
- [x] **Other (Drug or Compound Not Listed Above)**

4. * **Will the doses of drug administered and the dosing schedule match FDA approved labeling:** ***(if not, include all doses and dosing schedules in the Methods)***

- ○ Yes
- ○ No
- ● **Not Applicable**

5. * **Select who holds the Investigational New Drug (IND) application for the drug/biologic:**

- ○ External to VCU Sponsor or Investigator
- ○ VCU Sponsor-Investigator
- ○ VCU Sponsor who is not the Investigator
- ● **Not Required**

6. **Indicate the drug's IND number, if applicable. If the drug qualifies for IND exemption, enter "IND Exempt":**

Bio-Medical Project Drugs

1. * **Drug:**
   Own brand cigarettes

2. * **Manufacturer:**
   Various Manufacturers

3. * **Select all types that apply:**

- [ ] FDA Approved and being used as approved
- [ ] Marketed Drug/Biologic Exempt from IND
- [ ] Investigational Drug/Biologic/Supplement used as drug
- [ ] Supplement
- [ ] Over the Counter Medication
- [x] **Other (Drug or Compound Not Listed Above)**

4. * **Will the doses of drug administered and the dosing schedule match FDA approved labeling:** ***(if not, include all doses and dosing schedules in the Methods)***

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- ○ No
- ● **Not Applicable**

5. * **Select who holds the Investigational New Drug (IND) application for the drug/biologic:**

- ○ External to VCU Sponsor or Investigator
- ○ VCU Sponsor-Investigator
- ○ VCU Sponsor who is not the Investigator
- ● **Not Required**

6. **Indicate the drug's IND number, if applicable. If the drug qualifies for IND exemption, enter "IND Exempt":**

Bio-Medical Project Drugs

1. * **Drug:**
   NJOY Ace 2.4% nicotine - Classic Tobacco (flavor)

2. * **Manufacturer:**
   NJOY LLC

3. * **Select all types that apply:**

- [x] **FDA Approved and being used as approved**
- [ ] Marketed Drug/Biologic Exempt from IND
- [ ] Investigational Drug/Biologic/Supplement used as drug
- [ ] Supplement
- [ ] Over the Counter Medication
- [ ] Other (Drug or Compound Not Listed Above)

4. * **Will the doses of drug administered and the dosing schedule match FDA approved labeling:** ***(if not, include all doses and dosing schedules in the Methods)***

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- ○ No
- ● **Not Applicable**

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- ○ External to VCU Sponsor or Investigator
- ○ VCU Sponsor-Investigator
- ○ VCU Sponsor who is not the Investigator
- ● **Not Required**

6. **Indicate the drug's IND number, if applicable. If the drug qualifies for IND exemption, enter "IND Exempt":**

Bio-Medical Project Drugs

1. * **Drug:**
   NJOY Ace 5.0% nicotine - Menthol (flavor)

2. * **Manufacturer:**
   NJOY LLC

3. * **Select all types that apply:**

- [ ] FDA Approved and being used as approved
- [ ] Marketed Drug/Biologic Exempt from IND
- [ ] Investigational Drug/Biologic/Supplement used as drug
- [ ] Supplement
- [ ] Over the Counter Medication
- [x] **Other (Drug or Compound Not Listed Above)**

4. * **Will the doses of drug administered and the dosing schedule match FDA approved labeling:** ***(if not, include all doses and dosing schedules in the Methods)***

- ○ Yes
- ○ No
- ● **Not Applicable**

5. * **Select who holds the Investigational New Drug (IND) application for the drug/biologic:**

- ○ External to VCU Sponsor or Investigator
- ○ VCU Sponsor-Investigator
- ○ VCU Sponsor who is not the Investigator
- ● **Not Required**

6. **Indicate the drug's IND number, if applicable. If the drug qualifies for IND exemption, enter "IND Exempt":**

Bio-Medical Project Drugs

1. * **Drug:**
   NJOY Ace 5.0% nicotine - Classic Tobacco (flavor)

2. * **Manufacturer:**
   NJOY LLC

3. * **Select all types that apply:**

- [x] **FDA Approved and being used as approved**
- [ ] Marketed Drug/Biologic Exempt from IND
- [ ] Investigational Drug/Biologic/Supplement used as drug
- [ ] Supplement
- [ ] Over the Counter Medication
- [ ] Other (Drug or Compound Not Listed Above)

4. * **Will the doses of drug administered and the dosing schedule match FDA approved labeling:** ***(if not, include all doses and dosing schedules in the Methods)***

- ○ Yes
- ○ No
- ● **Not Applicable**

5. * **Select who holds the Investigational New Drug (IND) application for the drug/biologic:**

- ○ External to VCU Sponsor or Investigator
- ○ VCU Sponsor-Investigator
- ○ VCU Sponsor who is not the Investigator
- ● **Not Required**

6. **Indicate the drug's IND number, if applicable. If the drug qualifies for IND exemption, enter "IND Exempt":**

Bio-Medical Project Drugs

1. * **Drug:**
   NJOY Daily 6% nicotine - Menthol (flavor)

2. * **Manufacturer:**
   NJOY LLC

3. * **Select all types that apply:**

- [ ] FDA Approved and being used as approved
- [ ] Marketed Drug/Biologic Exempt from IND
- [ ] Investigational Drug/Biologic/Supplement used as drug
- [ ] Supplement
- [ ] Over the Counter Medication
- [x] **Other (Drug or Compound Not Listed Above)**

4. * **Will the doses of drug administered and the dosing schedule match FDA approved labeling:** ***(if not, include all doses and dosing schedules in the Methods)***

- ○ Yes
- ○ No
- ● **Not Applicable**

5. * **Select who holds the Investigational New Drug (IND) application for the drug/biologic:**

- ○ External to VCU Sponsor or Investigator
- ○ VCU Sponsor-Investigator
- ○ VCU Sponsor who is not the Investigator
- ● **Not Required**

6. **Indicate the drug's IND number, if applicable. If the drug qualifies for IND exemption, enter "IND Exempt":**

Bio-Medical Project Drugs

1. * **Drug:**
   NJOY Daily 6% nicotine - Extra Rich Tobacco (flavor)

2. * **Manufacturer:**
   NJOY LLC

3. * **Select all types that apply:**

- [x] **FDA Approved and being used as approved**
- [ ] Marketed Drug/Biologic Exempt from IND
- [ ] Investigational Drug/Biologic/Supplement used as drug
- [ ] Supplement
- [ ] Over the Counter Medication
- [ ] Other (Drug or Compound Not Listed Above)

4. * **Will the doses of drug administered and the dosing schedule match FDA approved labeling:** ***(if not, include all doses and dosing schedules in the Methods)***

- ○ Yes
- ○ No
- ● **Not Applicable**

5. * **Select who holds the Investigational New Drug (IND) application for the drug/biologic:**

- ○ External to VCU Sponsor or Investigator
- ○ VCU Sponsor-Investigator
- ○ VCU Sponsor who is not the Investigator
- ● **Not Required**

6. **Indicate the drug's IND number, if applicable. If the drug qualifies for IND exemption, enter "IND Exempt":**

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   All participants

2. * **Select all that apply to this consent / assent group:**

	Name
☑	**Signed Consent by Participant**
☐	Signed Parent/Guardian Permission or Legally Authorized Representative Consent
☐	Signed Assent by Child or Decisionally Impaired Adult
☐	Verbal/Other Indication of Assent by Child or Decisionally Impaired Adult
☐	Short Form Consent (limited applicability)
☐	None of the Above (select waiver below)

3. * **Select all electronic signature platforms that apply to this consent / assent group:**
   - ☑ **Not using electronic signature platforms**
   - ☐ DocuSign Part 11 (FDA regulated studies)
   - ☐ DocuSign (standard platform for non-FDA regulated studies)
   - ☐ REDCap e-Consent
   - ☐ iMedConsent (Veterans Affairs studies)
   - ☐ Other electronic signature platform

4. **If Other is selected, explain:**

5. * **Select any waivers that apply to this consent / assent group:**

☑	**No Waivers Requested**
☐	Waiver of All Consent or Some Elements in Consent Form
☐	Waiver of Parental Permission or Legally Authorized Representative Consent
☐	Waiver of All Assent by Child or Decisionally Impaired Adult
☐	Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)
☐	Exception from Informed Consent (for emergency research only)

6. * **Select all study team role(s) that will obtain consent / assent from this group:**

☑	**Principal Investigator**
☑	**Co/Sub-Investigator**
☐	Medical or Psychological Responsible Investigator

- [ ] Lead Student/Trainee Investigator (leading their own project)
- [x] **Research Coordinator**
- [x] **Research Nurse**
- [ ] Consultant
- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [x] **Trainee/Student(working on project)**
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

7. * **Describe the consent procedures used for this group. Address each point below:**

    - When and where consent will occur
    - What will be covered during the consent discussion
    - How the consent discussion will occur (e.g. in-person, phone, video conference)
    - How you will reconfirm consent on an ongoing basis, if applicable

    Consent will be obtained in a private room located at the Center for the Study of Tobacco Products (CSTP). Consent will be obtained at in-person screening. Consent will be on-going and assumed when a participant makes and completes follow up appointments. Participants are read the consent form aloud via a pre-recorded voice-over Powerpoint presentation/video or in real-time by a staff member and encouraged to ask questions before signing. At any point participants can chose not to continue with the various levels of screening for this study (the online/telephone consent/screening and in-person consent/screening).

8. * **Select the processes for minimizing any potential perception of undue influence to participate, particularly when there is a pre-existing relationship between the participant and the researcher (e.g. treatment provider/patient; instructor/student; supervisor/employee, etc.):**
    - [ ] Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion
    - [ ] Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion
    - [x] **Removing physical symbols of authority like white coats or police badges**
    - [x] **Sitting down beside the participant instead of standing over them**
    - [ ] If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)
    - [ ] Moving to a more neutral location like a conference room
    - [ ] Obtaining consent / assent after other services/interactions have been completed (e.g. after school or the clinic visit)
    - [ ] Having a mandatory wait period for the participant to go home and think before they sign consent /assent
    - [ ] Sharing the consent / assent discussion between two people (i.e. a clinician might be the best person to explain study procedures and risks, but then they could step out and let a research assistant finish the consent process)
    - [x] **Other protection(s) not listed here – describe below**
    - [ ] N/A: Requesting Waiver of Consent

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
    The consent form emphasizes the voluntary nature of the research study and staff are well-trained to ensure individuals understand their rights as a research participant. A copy of the consent form is given to all potential

participants to take with them. They are informed that that they can go home and/or discuss their participation with others prior to signing the form.

10. * **How much time will participants be given to make a decision:**
    Participants will be given as much time as necessary to consider the research study and consent form before deciding whether or not to participate.

11. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**

Personnel

1. * **Name:**
   Caroline Cobb Amey

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

   - [x] **Principal Investigator**
   - [ ] Co/Sub-Investigator
   - [ ] Medical or Psychological Responsible Investigator
   - [ ] Lead Student/Trainee Investigator (leading their own project)
   - [ ] Research Coordinator
   - [ ] Research Nurse
   - [ ] Consultant
   - [ ] Research Assistant
   - [ ] Pharmacist
   - [ ] Statistician
   - [ ] Regulatory Coordinator
   - [ ] Trainee/Student(working on project)
   - [ ] Other

4. * **Study related responsibilities:**

   - [x] **Study Design**
   - [x] **Data Collection - Lab**
   - [ ] Data Collection - Clinical
   - [x] **Data Collection - Interviews/Surveys**

- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [x] **Data Entry**
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [x] **Project Coordination**
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Andrew Barnes

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

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   - (●) **Yes**
   - ( ) No

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- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Alison Breland

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

   - [ ] Principal Investigator
   - [x] **Co/Sub-Investigator**
   - [ ] Medical or Psychological Responsible Investigator
   - [ ] Lead Student/Trainee Investigator (leading their own project)
   - [ ] Research Coordinator
   - [ ] Research Nurse
   - [ ] Consultant
   - [ ] Research Assistant
   - [ ] Pharmacist
   - [ ] Statistician
   - [ ] Regulatory Coordinator
   - [ ] Trainee/Student(working on project)
   - [ ] Other

4. * **Study related responsibilities:**

   - [x] **Study Design**
   - [x] **Data Collection - Lab**
   - [ ] Data Collection - Clinical
   - [x] **Data Collection - Interviews/Surveys**

- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [x] **Data Entry**
- [x] **Data Coding**
- [ ] Data Management
- [x] **Data Analysis**
- [x] **Project Coordination**
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Thomas Eissenberg

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

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   - (●) **Yes**
   - ( ) No

3. * **Roles:**

   - [ ] Principal Investigator
   - [x] **Co/Sub-Investigator**
   - [ ] Medical or Psychological Responsible Investigator
   - [ ] Lead Student/Trainee Investigator (leading their own project)
   - [ ] Research Coordinator
   - [ ] Research Nurse
   - [ ] Consultant
   - [ ] Research Assistant
   - [ ] Pharmacist
   - [ ] Statistician
   - [ ] Regulatory Coordinator
   - [ ] Trainee/Student(working on project)
   - [ ] Other

4. * **Study related responsibilities:**

   - [x] **Study Design**
   - [ ] Data Collection - Lab
   - [ ] Data Collection - Clinical
   - [ ] Data Collection - Interviews/Surveys

- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [ ] Data Entry
- [ ] Data Coding
- [x] **Data Management**
- [x] **Data Analysis**
- [ ] Project Coordination
- [x] **Participant Identification**
- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Thokozeni Lipato

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

   - [ ] Principal Investigator
   - [ ] Co/Sub-Investigator
   - [x] **Medical or Psychological Responsible Investigator**
   - [ ] Lead Student/Trainee Investigator (leading their own project)
   - [ ] Research Coordinator
   - [ ] Research Nurse
   - [ ] Consultant
   - [ ] Research Assistant
   - [ ] Pharmacist
   - [ ] Statistician
   - [ ] Regulatory Coordinator
   - [ ] Trainee/Student(working on project)
   - [ ] Other

4. * **Study related responsibilities:**

   - [ ] Study Design
   - [ ] Data Collection - Lab
   - [ ] Data Collection - Clinical
   - [ ] Data Collection - Interviews/Surveys

- [ ] Data Collection - Direct Observation
- [x] **Clinical Services**
- [ ] Intervention Services
- [x] **Data Entry**
- [ ] Data Coding
- [x] **Data Management**
- [ ] Data Analysis
- [ ] Project Coordination
- [x] **Participant Identification**
- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Yes

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Nicoleta Gaitan

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ○ Yes
   ● **No**

3. * **Roles:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [x] **Research Nurse**
- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other

4. * **Study related responsibilities:**

- [ ] Study Design
- [ ] Data Collection - Lab
- [ ] Data Collection - Clinical
- [ ] Data Collection - Interviews/Surveys

- [ ] Data Collection - Direct Observation
- [x] **Clinical Services**
- [ ] Intervention Services
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis
- [x] **Project Coordination**
- [ ] Participant Identification
- [x] **Participant Recruitment**
- [ ] Participant Consent
- [ ] Regulatory Management
- [x] **Other**

5. * **If other responsibility is selected, explain:**
   Provide medical safety supervision/consultation

6. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Yes

7. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

8. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Rabia Imran

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

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   ○ Yes
   ● **No**

3. * **Roles:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other

4. * **Study related responsibilities:**

- [ ] Study Design
- [x] **Data Collection - Lab**
- [ ] Data Collection - Clinical
- [x] **Data Collection - Interviews/Surveys**

- [x] **Data Collection - Direct Observation**
- [ ] Clinical Services
- [ ] Intervention Services
- [x] **Data Entry**
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [x] **Project Coordination**
- [ ] Participant Identification
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Augustus White

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

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   ○ Yes
   ● **No**

3. * **Roles:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [x] **Trainee/Student(working on project)**
- [ ] Other

4. * **Study related responsibilities:**

- [ ] Study Design
- [x] **Data Collection - Lab**
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- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
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- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Rose Bono

2. * **Is this individual a 'COI Investigator'?**

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   ○ Yes
   ● **No**

3. * **Roles:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
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- [ ] Research Nurse
- [ ] Consultant
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- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
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- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
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Individual has no clinical responsibilities

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- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Mary Bridgman

2. * **Is this individual a 'COI Investigator'?**

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   ○ Yes
   ● **No**

3. * **Roles:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
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- [x] **Data Collection - Lab**
- [ ] Data Collection - Clinical
- [x] **Data Collection - Interviews/Surveys**

- [x] **Data Collection - Direct Observation**
- [ ] Clinical Services
- [ ] Intervention Services
- [x] **Data Entry**
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- [x] **Data Management**
- [x] **Data Analysis**
- [x] **Project Coordination**
- [ ] Participant Identification
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Yes

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Melody Falter

2. * **Is this individual a 'COI Investigator'?**

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   ○ Yes
   ● **No**

3. * **Roles:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other

4. * **Study related responsibilities:**

- [ ] Study Design
- [x] **Data Collection - Lab**
- [ ] Data Collection - Clinical
- [x] **Data Collection - Interviews/Surveys**

- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [x] **Data Entry**
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- [x] **Data Management**
- [x] **Data Analysis**
- [x] **Project Coordination**
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

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- [x] **Experience - Research**
- [ ] Experience - Clinical
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Carrico

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

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   ○ Yes
   ● **No**

3. * **Roles:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [x] **Trainee/Student(working on project)**
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4. * **Study related responsibilities:**

- [ ] Study Design
- [x] **Data Collection - Lab**
- [ ] Data Collection - Clinical
- [x] **Data Collection - Interviews/Surveys**

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- [ ] Intervention Services
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- [ ] Regulatory Management
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- [x] **Experience - Research**
- [ ] Experience - Clinical
- [x] **Experience - Related Skills**
- [ ] Trainee
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Elizabeth Ogunleye

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

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   ○ Yes
   ● **No**

3. * **Roles:**

- ☐ Principal Investigator
- ☐ Co/Sub-Investigator
- ☐ Medical or Psychological Responsible Investigator
- ☐ Lead Student/Trainee Investigator (leading their own project)
- ☐ Research Coordinator
- ☐ Research Nurse
- ☐ Consultant
- ☐ Research Assistant
- ☐ Pharmacist
- ☐ Statistician
- ☐ Regulatory Coordinator
- ☑ **Trainee/Student(working on project)**
- ☐ Other

4. * **Study related responsibilities:**

- ☐ Study Design
- ☑ **Data Collection - Lab**
- ☐ Data Collection - Clinical
- ☑ **Data Collection - Interviews/Surveys**

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- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
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- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

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- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [x] **Experience - Related Skills**
- [ ] Trainee
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**

Add Document

1. * **Document Name:**
   Informed Consent

2. * **Type:**
   Consent/Assent/Information Sheet

3. * **File:**
   P3 TASTE_Informed Consent_CLEAN_1.29.2024.pdf(0.15)

Add Document

1. * **Document Name:**
   Consent - Tool

2. * **Type:**
   Consent/Assent/Information Sheet

3. * **File:**
   P3TASTE_Consent_Presentation_1.29.2024.pptx(0.06)

Add Document

1. * **Document Name:**
   Social Media Plan

2. * **Type:**
   Recruitment/Advertising

3. * **File:**
   P3-TASTE Social Media Plan_10.2.2023.docx(0.01)

Add Document

1. * **Document Name:**
   Social Media and Craigslist Ads

2. * **Type:**
   Recruitment/Advertising

3. * **File:**
   P3-TASTE_facebook and craiglist ads_10.2.2023.docx(0.01)

Add Document

1. * **Document Name:**
   Substance Use Resources Handout

2. * **Type:**
   Other

3. * **File:**
   CSTP Substance Use Resources_8.11.2023.docx(0.01)

Add Document

1. * **Document Name:**
   Subjective Measures

2. * **Type:**
   Research Measure

3. * **File:**
   P3-TASTE-Session Subjective Measures_CLEAN_08.09.2023.doc(0.03)

Add Document

1. * **Document Name:**
   P3 TASTE Advertisement for CSTP Website

2. * **Type:**
   Recruitment/Advertising

3. * **File:**
   P3 TASTE - CSTP Website Study Description_CLEAN_08.08.2023.docx(0.05)

Add Document

1. * **Document Name:**
   Presession Symptom Questions

2. * **Type:**
   Research Measure

3. * **File:**
   P3-Presession symptom Checklist-CLEAN_08.09.2023.docx(0.05)

Add Document

1. * **Document Name:**
   Baseline Self Report Physio Measures

2. * **Type:**
   Research Measure

3. * **File:**
   P3-TASTE_Baseline forms All_CLEAN_8.11.2023.docx(0.06)

Add Document

1. * **Document Name:**
   Text, Email, Call Scripts

2. * **Type:**
   Study reminders/communications

3. * **File:**
   P3-TASTE_Phone_e-mail_text scripts_08.09.2023_CLEAN.docx(0.10)

Add Document

1. * **Document Name:**
   Referral Program Card Template

2. * **Type:**
   Recruitment/Advertising

3. * **File:**
   P3_Referral program card_06.02.2023_CLEAN.docx(0.03)

Add Document

1. * **Document Name:**
   COVID-19 Questions

2. * **Type:**
   Other

3. * **File:**
   COVID_Questions_P3_no longer using.docx(0.02)

Add Document

1. * **Document Name:**
   P3 Taste_ETM

2. * **Type:**
   Research Measure

3. * **File:**
   P3-TASTE_Measures_ETM__no longer using.docx(0.04)

Add Document

1. * **Document Name:**
   Tobacco Cessation Resources Handout

2. * **Type:**
   Other

3. * **File:**
   Cessation_handout_RI_04.29.2021.pdf(0.01)

Add Document

1. * **Document Name:**
   U54 Grant Application Without Budget

2. * **Type:**
   Funding Proposal

3. * **File:**
   U54 Grant Application BUDGET PAGES DELETED FOR IRB.pdf(0.01)

Add Document

1. * **Document Name:**
   CP-DPT & DPT

2. * **Type:**
   Research Measure

3. * **File:**
   P3-TASTE Drug Purchase Tasks_9.2.2022.docx(0.01)

Add Document

1. * **Document Name:**
   CP-DPT & DPT - Tool

2. * **Type:**
   Research Measure

3. * **File:**
   DPT_CDPT presentation_10.28.2022.pptx(0.01)

Add Document

1. * **Document Name:**
   Subjective Measures -Tool

2. * **Type:**
   Research Measure

3. * **File:**
   Subjective Measures presentation_10.28.2022.pptx(0.01)

Add Document

1. * **Document Name:**
   Barnes Biosketch

2. * **Type:**
   CV/Biosketch

3. * **File:**
   P3 Barnes biosketch 06.22.17.FINAL.docx(0.01)

Add Document

1. * **Document Name:**
   Lipato Biosketch

2. * **Type:**
   CV/Biosketch

3. * **File:**
   Lipato Biosketch.pdf(0.01)

Add Document

1. * **Document Name:**
   Caroline Cobb (Amey) CV

2. * **Type:**
   CV/Biosketch

3. * **File:**
   CV_Cobb_August 2022.docx(0.01)

Add Document

1. * **Document Name:**
   Baseline Discounting Task - MDT

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Overall Research Strategy. In 2009, FDA began regulating some tobacco products and, in 2016, extended its regulatory authority to others, including electronic cigarettes (ECIGs). ECIGs heat a liquid that usually contains nicotine; users inhale the resulting aerosol. Regulating tobacco products is challenging, in part because a potential health-promoting regulation can have unintended consequences that impact public health negatively. For example, requiring "tar" and nicotine yields on cigarette packs was intended to provide health-promoting information to smokers, but drove some of them to switch to "low yield" cigarettes instead of quitting smoking, thus increasing their risk of tobacco-caused disease (NCI, 2001). As FDA considers future regulatory actions on the variety of products now under its jurisdiction, it may benefit from data-driven models that allow it to predict efficiently and accurately the population-level consequences of the potential action it is considering. For this reason, the Center for the Study of Tobacco Products (CSTP) proposes four projects with an integrative theme of impact analysis, drawing on our established expertise in the scientific domains of tobacco product toxicity, user behavior, and addiction/abuse liability. Our vision is to provide FDA with tools that can be used to guide regulation development. Importantly, to realize this vision, we do not require foreknowledge of potential FDA regulatory action or any tobacco regulatory changes. Rather, our approach involves identifying three potential regulatory actions (described below) and then examining hypotheses about those actions under the controlled conditions of Projects 1-3. Results will be used to generate population-level predictions about current ECIG user behavior, and Project 4 will use a prospective cohort survey to test those predictions at the population level. We also propose an Administrative Core, a Career Enhancement Core, and a Contextual Knowledge Core that will inform Projects 1-4 (see "Administrative Structure", Fig 1, in *Administrative Core*).

A. Overall Significance. FDA's authority to regulate tobacco products arises from the Family Smoking Prevention and Tobacco Control Act that states that a primary goal of tobacco regulation is to protect public health. This "public health standard" requires FDA to consider how regulation will influence the risks and benefits to tobacco product users and non-users. Among other things, FDA must be cognizant of regulatory impact on the likelihood of cessation and transitions across tobacco products for current users, and the likelihood of initiation of tobacco use among non-users. These issues are relevant to all tobacco products, and particularly salient for ECIGs as their popularity increases. For example, among US high school students, in whom past 30-day ECIG use was 16% in 2015 – up 900% from 2011 – ECIGs are more popular than tobacco cigarettes (USDHHS, 2016). Among young adults ages 18-24, ECIG prevalence is 13% (USDHHS, 2016) and they are as common among never smokers as among current smokers (Schoenborn & Gindi, 2016). As the Surgeon General noted, "E-cigarette use among U.S. youth and young adults is now a major public health concern" (USDHHS, 2016, p. vii). Addressing this public health concern through regulation will be challenging for at least two reasons. First, ECIGs are a class of products that evolve constantly and vary greatly in many characteristics, such as liquid nicotine concentration, device power, and liquid flavors (USDHHS, 2016). These characteristics can influence ECIG effects including toxicant emissions (e.g., Breland et al., 2017) and also can influence ECIG abuse liability (i.e., increased likelihood of persistent use and dependence; Carter et al., 2009). Second, ECIG user behavior is variable. Puff behavior (i.e., puff topography, including puff number and duration) helps to determine the amount nicotine delivered to the user and thus ECIG subjective effects (e.g., Hiler et al., in press). Potential FDA regulatory action intended to influence ECIG effects in users and initiation in non-users must therefore account for variability in product characteristics and user behavior.

If FDA is to understand how tobacco product regulation will influence the risks and benefits to users and non-users, it may benefit from robust scientific methods that predict how variability in product characteristics and user behavior will influence the impact of regulatory action. To understand the benefit of predicting regulatory impact, consider the European Union's (EU's) Tobacco Products Directive 2014/40/EU that limits ECIG liquids to no more than 20 mg/ml nicotine to allow "for a delivery of nicotine that is comparable to the permitted dose of nicotine derived from a standard cigarette…". (http://ec.europa.eu/health/tobacco/products_en). The intended consequence of this directive is clear: limiting liquid concentration to ≤20mg/ml is supposed to limit nicotine delivery to the user such that delivery does not exceed that of a tobacco cigarette. However, the directive does not account for variability in product characteristics that work against its intent and, in fact, may increase public health risk. Device power (measured in watts, or W) influences ECIG nicotine emissions (Talih et al., 2015; Sleiman et al., 2016): early ECIG models were powered at 10 W or less, but current models achieve 150 W or more (Wagener et al., 2017). Recent data from a small convenience sample demonstrate that 10 puffs from high power ECIGs (mean=70 W) filled with only 4 mg/ml nicotine liquid (on average) can attain and sometimes exceed the nicotine delivery of a tobacco cigarette (Wagener et al., 2017). Use of these

"third generation" ECIGs is on the rise (e.g., Barrington-Trimis et al., 2017), and early results reveal that, relative to lower power devices, they can produce more carcinogenic volatile aldehydes (Gillman et al., 2016; El-Hellani et al., 2016), lead users to consume more nicotine-containing liquid (Wagener et al., 2017; Etter, 2016; Sleiman et al., 2016), and, due to their ability to deliver nicotine so effectively, likely have greater abuse liability. These results suggest that, when higher power devices are available, the intended consequences of the EU directive are unlikely to be realized and unintended consequences are likely because users can buy high power devices that produce more toxicants (i.e., increase toxicity), lead users to consume more liquid (i.e., alter behavior) and deliver nicotine more efficiently (i.e., increase abuse liability), even when paired with liquids ≤20 mg/ml nicotine. The ability to predict the consequences of regulatory action might help FDA craft regulations that meet their intent without increasing product toxicity, altering user behavior, and enhancing product abuse liability. Indeed, if FDA had scientific methods that could predict these population-level outcomes in advance, these methods could be used to generate objective data to guide the development of potential regulation. Then, by the time data-guided regulations are enacted, they will have been crafted to maximize intended effects and minimize unintended consequences. Our goal with this application is to provide these methods to FDA. To do so, we examine, under controlled conditions, hypotheses related to three potential regulatory actions: limiting liquid nicotine concentration, constraining nicotine flux (nicotine yield/unit time), and reducing flavor availability. We then use results from this controlled condition testing to generate predictions about how these potential regulatory actions might impact the population, and then test these predictions at the population level. Note that *no new regulations need be in place for us to meet these goals*.

What model are we using for impact analysis? There are a number of important outcomes to consider when attempting to predict the impact of potential tobacco product regulation, and not all can be considered at once. We focus on outcomes from three key domains: product toxicity (Project 1), user behavior (Project 2), and abuse liability (Project 3). Toxicity is relevant because, at a minimum, a regulation should not increase tobacco product toxicant emissions, and regulated changes in toxicant emissions can drive use of one product over another. User behavior is relevant because people may adapt to a regulated product in a way that defeats regulatory intent or increases product toxicity. Abuse liability is relevant because it is a key determinant of the extent to which current users will maintain persistent tobacco product use and, importantly, also may help determine transitions from one class of products (e.g., ECIGs) to another (e.g., tobacco cigarettes); it may also be predictive of tobacco initiation and persistent use among current non-users. Because toxicity, behavior, and abuse liability can interact (e.g., longer puffs can increase delivery of nicotine and other toxicants, thus influencing abuse liability as well as health effects) we emphasize a transdisciplinary approach in which these issues are considered simultaneously (see Fig 1, next page). We expand on each of these topics below.

Understanding product toxicity can help predict population-level effects. One powerful way to study tobacco product toxicity is to analyze emissions under controlled conditions. For example, to understand cigarette toxicity, cigarette smoke constituents were analyzed and found to contain many toxicants (USDHHS, 2010), including highly carcinogenic TSNAs. TSNAs can be controlled through manufacturing modifications (Chamberlain & Chortyk, 2015), leading to regulatory measures that have resulted in lower population-level TSNA exposure (e.g., Czoli & Hammond, 2017; Xia et al., 2011). Similarly, for waterpipe, smoke constituents have been analyzed and many cigarette smoke toxicants are found in waterpipe smoke (e.g., WHO, 2015). An analog of this approach that simulates the oral cavity has been applied to smokeless tobacco (e.g., Delvadia et al., 2012). Thus, analyzing toxicant emissions is relevant to an array of FDA-regulated tobacco products.

We and others have begun using this approach for ECIGs in ways that can inform regulation by analyzing the content of ECIG aerosols produced under controlled conditions (Bekki et al., 2014; Mikheev et al., 2016; Soussy et al., 2016). Results reveal fewer toxicants in ECIG aerosol relative to cigarette smoke (e.g., Margham et al., 2016), and also make clear that many factors influence ECIG nicotine and other toxicant emissions. As might be expected, ECIG nicotine emission is related directly to liquid nicotine concentration and it also is related to device power and puff duration (e.g. Talih et al., 2015). In fact, our nicotine emission analyses led us to develop a physics-based mathematical model that takes into account device, liquid, and puff variables and allows us to predict the amount of nicotine emitted/unit time (i.e., nicotine "flux", in μg/sec, R^2=0.72; Talih et al., 2016a). We have suggested that nicotine flux may be an important regulatory consideration (e.g., Shihadeh & Eissenberg, 2015), in that speed of drug delivery is a key factor in abuse liability (e.g., Henningfield & Keenen, 1993). Building on this suggestion, FDA might develop product standards that specify a range of nicotine flux values that approach but do not exceed the nicotine delivery of a tobacco cigarette: product standards are

squarely in the purview of FDA's authority to regulate tobacco product manufacturing. These flux standards could be attained by products that limit key characteristics like maximum and minimum wattage, liquid nicotine concentration, and puff duration (e.g., the device turns off after detecting a 3-sec puff, and does not allow another puff for 20 seconds). However, such standards must also take into account the observation that device, liquid, and puff variables are relevant to ECIG emissions of non-nicotine toxicants. For example, increasing ECIG power from 4.1 to 8.8 W approximately tripled volatile aldehyde emissions (Sleiman et al., 2016; see also Wang et al., 2017; Havel et al., 2016; Geiss et al., 2016) and, in another study, increasing power from 4.3 to 10.8 W more than doubled furan emissions (Soussy et al., 2016). Also, increasing ECIG power from 6 to 13 W increased emissions of the carcinogen benzene 100-fold (Pankow et al., 2017). These results suggest that, if nicotine flux is used as a regulatory target, care must be taken: there may be some flux conditions that meet the nicotine target and that also emit more non-nicotine toxicants relative to other conditions that meet the same target. Another factor that influences ECIG toxicant emissions involves flavorants (e.g., Soussy et al., 2016; Behar et al., 2016). In some cases, flavorant inhalation could have health consequences (e.g., Farsalinos et al., 2015; Leigh et al., 2016). In sum, one way to understand tobacco product toxicity is to produce emissions under controlled conditions and analyze their content. These methods have been used to understand toxicity of cigarettes, waterpipes, and smokeless tobacco, and are being applied to understanding toxicity of ECIGs. Extant data indicate that factors that influence ECIG nicotine and other toxicant emissions include liquid nicotine concentration, device power, puff duration, and liquid flavorants.

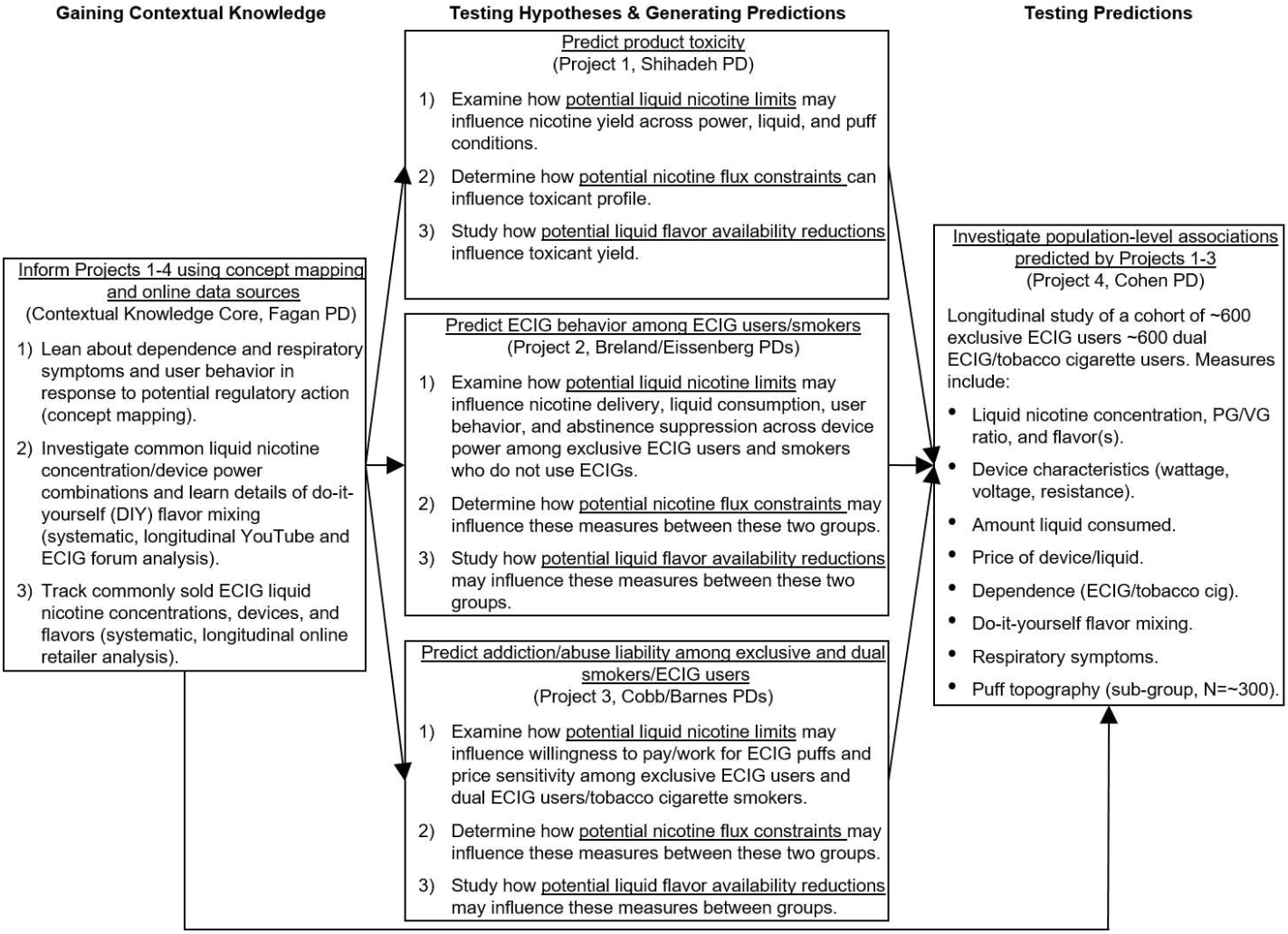

Figure 1: Model for predicting potential regulatory impact. A Contextual Knowledge Core informs Projects 1-3 about common ECIG wattages, nicotine concentrations, and flavors as well as do-it-yourself (DIY) flavor recipes/methods; it also informs Project 4's respiratory effects and dependence assessment. Projects 1-3 will test hypotheses concerning three potential regulatory actions. Project 1 tests hypotheses regarding the toxicant content of ECIG aerosols, Project 2 tests hypotheses regarding user behavior and toxicant exposure, and Project 3 tests hypotheses regarding abuse liability. Project 1-3 results are used to generate predictions regarding population-level phenomena. Project 4 uses a prospective cohort survey to test predictions, examining relationships between device power and nicotine concentration, nicotine flux and dual use and respiratory symptoms, and flavor availability and DIY flavor mixing.

The same methods used to understand tobacco product toxicity also can help generate predictions regarding population-level effects of potential tobacco product regulation. For example, consider again Directive 2014/40/EU that limits ECIG liquid nicotine concentration to ≤20 mg/ml. If FDA contemplated similar action, one approach to predict its effects would be to examine ECIG emissions under relevant controlled conditions. These conditions could involve varying liquid nicotine concentration as well as other factors such as device power and puff duration. Based on limited data available now, higher powered devices paired with lower nicotine liquids likely emit nicotine in amounts that exceed a tobacco cigarette (e.g., Talih et al., 2015). Moreover, these pairings of high power/low nicotine likely lead to greater non-nicotine toxicant production (El-Hellani et al., 2016) and aerosolize more liquid (e.g., Sleiman et al., 2016). At the population level, this pattern suggests that individuals who use higher power ECIGs consume more aerosolized liquid and may also report more adverse events (e.g., respiratory symptoms) due to greater toxicant inhalation. Next, consider regulating nicotine flux within a target range (e.g., Shihadeh & Eissenberg, 2015) and a study that examines ECIG toxicant emissions across that range. A given nicotine flux standard can be met in numerous ways, including decreasing liquid nicotine concentration while increasing power, but increased power can increase non-nicotine toxicant emissions. Thus, users of some products that can meet the flux standard might be exposed to more toxicants than others who use different products that also can meet that same standard. At the population level, this observation suggests that users of high power/low nicotine combinations will experience more adverse events than would users of low power/high nicotine combinations even though both achieve similar nicotine flux. Finally, consider a regulation that reduces the availability of ECIG liquid flavors. ECIG users are known to engage in do-it-yourself (DIY) flavor mixing (e.g., Farsalinos et al., 2014; Etter, 2016), and decreased flavor availability may increase DIY likelihood. Common DIY flavors can be mixed in the lab and the toxicity of their aerosols evaluated under controlled conditions. To the extent that DIY liquids produce more aerosolized toxicants than others, DIY liquid users might be expected to report more adverse events. Each of these potential regulatory actions are reasonable policy approaches to ECIGs, and each of the predicted population-level effects are possible consequences of them. Examining the effects of these potential regulatory actions on product toxicity is the work of our Project 1. What is missing is some way of testing population-level predictions to determine if they represent real-world phenomena. We return to this topic two pages down.

Understanding user behavior can help predict population-level effects. One powerful way to study tobacco user behavior is with the methods of the clinical lab, where tobacco users are presented with various products under controlled conditions and key outcomes such as subjective effects, topography (e.g., puff volume and duration), and nicotine delivery are measured. There is a large literature detailing this approach using cigarettes (Hammond et al., 2005; Rose & Behm, 2004, Collins et al., 2010), waterpipe (e.g., Blank et al., 2011; Leavens et al., 2017; WHO, 2015), smokeless tobacco (e.g., Hatsukami et al., 2011, Lemmonds et al., 2005; Gire & Eissenberg, 2000; Lunell & Curvall, 2011), and non-cigarette products that emit aerosol (e.g., Breland et al., 2002; Lopez et al., 2016a). Results are too numerous to detail, but demonstrate, for example: 1) that “low-yield” cigarettes cause smokers to take longer and larger puffs that influence nicotine and other toxicant delivery (e.g., Djordjevic et al., 2000); 2) that, relative to a cigarette, a waterpipe session is associated with puffs that are 10 times larger, carbon monoxide exposure that is 4 times greater, and nicotine exposure that does not differ (e.g., Cobb et al., 2011); 3) that smokeless tobacco product pH influences nicotine delivery and physiological response (Pickworth et al., 2014) and 4) that smokeless tobacco products marketed to cigarette smokers fail to suppress aversive tobacco abstinence effects in smokers (e.g., Blank & Eissenberg, 2010; Cobb et al., 2010). Thus, measures of user behavior are relevant to a broad array of FDA-regulated products (i.e., inhaled and oral). They are also predictive of real-world behavior (e.g., Breland et al., 2002).

We and others have begun informing ECIG regulation by studying the factors that influence ECIG user subjective response, puffing behavior, and nicotine exposure (e.g., Cox et al., 2016; Dawkins & Corcoran, 2014; Eissenberg, 2010; Hajek et al., 2015; Papaseit et al., 2017). For example, the effects of nicotine liquid concentration have been examined in several studies (e.g., St. Helen et al., 2016; Vansickel & Eissenberg, 2013). In two studies where liquid nicotine concentration was manipulated systematically, 16 smokers (Lopez et al., 2016c) and 16 ECIG users (Ramôa et al., 2016) completed 10-puff use bouts with a 7.3 W device loaded with 0, 8, 18, or 36 mg/ml nicotine liquid. Results demonstrated that plasma nicotine concentration increased with liquid nicotine concentration, but nicotine delivery was greater for experienced ECIG users. For example, at 36 mg/ml, mean post-bout plasma nicotine was 30.2 ng/ml (SD=20.0) for ECIG users (Ramôa et al., 2016a) compared to 17.0 ng/ml (SD=17.9) for smokers (Lopez et al., 2016c). This result may be explained by the

finding that experienced ECIG users took longer puffs (e.g., at 36 mg/ml, mean puff duration was 4.0 s for ECIG users and 2.3 s for cigarette smokers). In a study that compared subjective effects, puff topography, and nicotine delivery across experienced ECIG users and ECIG-naïve cigarette smokers, the magnitude of a variety of subjective effects also increased as nicotine concentration increased (as did plasma nicotine concentration), with between group differences in subjective effects (including tobacco/nicotine abstinence symptom suppression), plasma nicotine concentration, and puff topography (Hiler et al., in press). These same outcomes can be used to examine the effects of potential FDA regulation.

Results from clinical lab studies in which user behavior is measured can help generate predictions regarding the population-level effects of potential tobacco product regulation. For example, if a clinical lab study in which device power and nicotine concentration are manipulated reveals that low power/low nicotine combinations fail to suppress aversive nicotine abstinence symptoms and increases puff duration and volume, a regulation that limits nicotine concentration might be predicted to cause ECIG users either to take longer, larger puffs from their current device, or switch to higher powered devices that emit more aerosol, with a resulting increase in daily liquid consumption. Similarly, if a study in which flux is manipulated reveals that high flux conditions deliver nicotine and suppress abstinence symptoms effectively while low flux conditions do not, then high flux conditions may be more associated with population-level exclusive ECIG use and low flux conditions with population-level dual ECIG/cigarette use. Likewise, if a clinical lab study in which flavor is manipulated reveals that preferred flavors are associated with greater abstinence symptom suppression and nicotine delivery, ECIG users at the population level might be expected to either report more abstinence symptoms and consume less liquid when their preferred flavor is unavailable, or find ways to attain that preferred flavor regardless of its availability (e.g., DIY flavor mixing). Thus, behavioral outcomes can help predict population-level phenomena. This topic is the work of our Project 2. There remains a need to test population-level predictions to determine if they represent real-world phenomena. We return to this topic at the bottom of the next page.

Understanding abuse liability can help predict population-level effect. Cigarette smokers know that smoking is lethal, but quitting is difficult because they self-administer the dependence-producing drug nicotine with every toxicant-laden puff. For this reason, understanding dependence/addiction is a key element in treating and preventing tobacco use (USDHHS, 2010). Doing so requires an understanding of drug reinforcement: how rewarding a drug is and how likely it is to sustain persistent use and dependence (e.g., IOM, 2012; Hanoch et al., 2017). The likelihood that a given drug's reinforcement value will lead to persistent use and dependence is part of its overall "abuse liability" (e.g., Carter & Griffiths, 2009), and this abuse liability concept has been applied to tobacco (Carter et al., 2009). There is a growing understanding that combustible tobacco cigarettes lie at the upper end of the reinforcement continuum among drugs of abuse (e.g., IOM, 2012). The issues raised by the application of abuse liability to tobacco product regulation have been articulated and include (but are not limited to) a product's ability to promote switching to that product and cessation of a more harmful one; dual use of the less and more harmful products; and relapse in current exclusive users of the less harmful product to occasional or exclusive use of the more harmful one (IOM, 2012): "All of these outcomes can be logically related to the [product's] reinforcing value … (how rewarding it is)." (IOM, 2012; p.149). These issues are of particular importance for regulation of ECIGs that are sometimes used exclusively by former cigarette smokers who have switched to ECIGs but are more often used by current tobacco smokers *in conjunction with* tobacco cigarettes (i.e., dual use; USDHHS, 2016). Critically, important methods for predicting a tobacco product's abuse liability include lab-based behavioral economic indicators of demand for a single product and substitution between products (IOM, 2012). One of the most policy-relevant behavioral economic predictors of tobacco product abuse liability is own-price elasticity of demand. Elasticity provides an index of a tobacco product's value to a user. For example, users who are less elastic will be less responsive to policies that make tobacco products harder to obtain. Thus, lower elasticity is a predictor of higher abuse liability (Hursh & Roma, 2013; Hursh & Winger, 1995; Hursh & Silberberg, 2008; Carter et al., 2009). By extension, assessing a tobacco product's value means measuring how much users are willing to pay to consume that product as well has how hard they are willing to work for it, and results can be used to predict population-level abuse liability. Moving beyond a single product, the economic relationship between two products (e.g., cigarettes and ECIGs) can be described using measures of cross-price elasticity, categorized along a continuum. Consider the case of two tobacco products whose reinforcing values are similar. Policies or regulations that make one product more difficult to obtain without influencing the other will result in users substituting away from the first by reducing their consumption and towards the second by increasing their consumption. Thus, regulatory action

aiming to influence the demand for one tobacco product will affect substitution in consumption for other tobacco products that are considered by users to have similar reinforcing value. Importantly, these patterns within and across tobacco products can be assessed in the lab and results can be used to predict product abuse liability at the population-level.

Lab-based testing with behavioral economic indicators has been used to examine normal cigarettes (Griffiths et al., 1996), very low nicotine cigarettes (Tucker et al., 2017), waterpipe (Salloum et al., 2015), and smokeless tobacco (Stein et al., 2017). For example, when smokers responded to a cigarette purchase task (CPT; it models tobacco consumption), purchases declined as cigarette price increased, with measures of own-price elasticity and the maximum amount participants were willing to pay corresponding to their nicotine dependence and daily smoking (MacKillop et al., 2008). Similarly, when demand for cigarettes and several substitutes (i.e., smokeless tobacco; medicinal nicotine) was assessed using purchase tasks, results revealed lower demand elasticity for cigarettes compared to all alternatives (O'Connor et al., 2014). This pattern suggests that changing smokers' cigarette availability would do little to influence demand for alternative nicotine sources (O'Connor et al., 2014). Another study estimated measures of demand for smokeless tobacco, as compared to cigarettes and nicotine gum, and demand for smokeless tobacco was significantly more elastic than for cigarettes (Stein et al., 2017). Thus, predicting tobacco product abuse liability using behavioral economic indicators in a lab setting is relevant to an array of FDA-regulated products (i.e., inhaled and oral) and may help explain user transitions across products, dual use, and exclusive use of one product over another.

We and others have begun using lab-based behavioral economic tasks to predict ECIG abuse liability (e.g., Grace et al., 2015; Copp et al., 2015; Czoli et al., 2016). For example, we compared smokers' choices for own-brand cigarette puffs, ECIG puffs, and money using a multiple-choice procedure (MCP) in which participants choose between puffs from a product and increasing dollar values (Vansickel et al., 2012). Smokers were willing to pay more for puffs from their own-brand cigarette than from ECIGs and they valued 10 ECIG puffs at 3 cigarette puffs. This pattern suggested lower abuse liability for these ECIGs relative to tobacco cigarettes. In another study with different ECIGs a similar pattern was observed (McPherson et al., 2016). One limitation of these studies is that they used early-model ECIGs that did not deliver nicotine effectively. More recently, we used the MCP and CPT among ECIG-naïve smokers to predict the abuse liability of ECIGs with a known nicotine delivery profile. Participants' willingness to pay for ECIGs was generally lower than for their own-brand tobacco cigarettes but these differences varied by ECIG liquid flavor (Barnes et al., 2017). Relatedly, another recent study demonstrated that young adult ECIG users will work harder for puffs from an ECIG loaded with flavored vs unflavored liquid, consistent with the notion that flavors likely increase ECIG abuse liability (Audrain-McGovern et al., 2016). Overall, these results demonstrate that behavioral economic tasks are a powerful tool to understand the abuse liability of ECIGs across potential regulatory conditions.

Results from lab-based behavioral economic studies can help generate predictions about population-level abuse liability in response to potential tobacco product regulation. For example, if a lab-based study in which device power and nicotine concentration are manipulated systematically predicts that lower power/nicotine combinations have lower abuse liability (i.e., participants exhibit greater price sensitivity), we would expect that, at the population-level, nicotine-dependent ECIG users will be more likely to seek out and buy higher power devices to maintain nicotine intake. Similarly, if a lab-based study in which nicotine flux is manipulated systematically reveals that flux is related directly to willingness to pay/work and inversely to price sensitivity and therefore predicts higher abuse liability, we would expect higher flux to be associated with more persistent use and greater nicotine dependence at the population level. Likewise, if a lab-based study examining abuse liability in which flavor is manipulated while nicotine flux is held constant reveals that participants are willing to pay more/work harder for their preferred flavor, we would expect that exclusive ECIG users will seek ways to attain that preferred flavor regardless of its availability on the market (e.g., DIY mixing). Thus, results from lab-based studies that employ behavioral economic indicators of abuse liability can be used to make population-level predictions regarding tobacco user behavior. This topic is the work of our Project 3. What is missing is some way of assessing population-level predictions of abuse liability generated in the lab in order to determine if those predictions represent real-world phenomena. We now turn to this topic.

<u>How can predictions regarding population-level impact be tested?</u> Many approaches have been used to evaluate the effects of enacted regulation. Quasi-experimental studies are often employed, with outcomes assessed before and after a jurisdiction enacts a regulation (Cook & Campbell, 1979; Borland, 1997). Stronger

designs compare outcomes before and after enactment across jurisdictions that did and did not enact the regulation, as epitomized by The International Tobacco Control (ITC) study (Thompson et al., 2006; Borland et al., 2009; Yong et al., 2017). ITC is multi-country and longitudinal and regularly assesses multiple measures related to regulatory constructs. While powerful policy evaluation tools, one limitation of these designs is that the regulation must already be in place, and then the regulation must be changed if it is not achieving its intended effects or has harmful unintended consequences. Simulation models can predict regulatory impact. For example, the SimSmoke model has been used to predict the impact of tobacco control policies on smoking prevalence and smoking attributable deaths (e.g., Levy et al., 2007; 2016). Modeling can also predict outcomes under different assumptions in the absence of requisite data (e.g., estimating the impact of ECIGs on smoking patterns; Levy et al., 2017). Monte Carlo simulations have been used to predict cigarette and ECIG use behaviors under different policy scenarios (e.g., Kalkhoran et al., 2015). A limitation of simulation models is that while they start with some actual data (e.g., effect size of a policy on smoking prevalence; prevalence of ECIG use), calculations are based on a range of assumptions that may or may not reflect real-world phenomena. The Population Assessment of Tobacco and Health (PATH) is a great resource for monitoring regulatory impact. It is a nationally representative longitudinal cohort study of U.S. youth and adults who are interviewed annually (Hyland et al., 2016). However, because PATH is nationally representative, it is not an efficient mechanism to gather detailed data from users of a specific product (e.g., ECIGs) when prevalence in the general population is relatively low. It also lacks many measures relevant to testing the impact of a potential regulation pertaining to a specific product (e.g., ECIG power).

We propose a data-driven method that will test population-level predictions generated by controlled testing using measures of product toxicity, user behavior, and abuse liability. We will recruit a cohort of ~1200 regular ECIG users and assess over time their device characteristics (wattage, voltage, resistance), liquid characteristics (nicotine concentration, PG/VG ratio, flavors), amount liquid consumed, price of current device/liquid, dependence (ECIG/tobacco cigarette), frequency of DIY flavor mixing, and respiratory symptoms. A sub-group of respondents will undergo puff topography measurement so that nicotine flux may be calculated. Importantly, predictions are tested by looking for anticipated associations at the population level (e.g., low nicotine liquids will be paired with high power devices and accompanied by greater dependence and respiratory symptoms). Thus, our testing does not require any new regulatory action. Also, while we are testing predictions we will also collect other data relevant to regulation, such as the rates at which ECIG users change their devices, nicotine concentration, and flavors. We also will use PATH data to explore our hypotheses, to the extent possible, particularly examining patterns of use and use behaviors among recent ECIG initiators. By comparing the sociodemographic distribution of our sample of regular ECIG users to the sociodemographic distribution among PATH ECIG users, we will be able to generate population-level estimates of our findings.

Summary. FDA's public health standard requires consideration of whether a potential regulation will meet its health-promoting intent without leading to harmful unintended consequences. This consideration, we suggest, should include empirical testing of the potential regulation's effects on product toxicity, as well as user behavior and behavioral economic indicators of abuse liability in relevant populations. We speculate that results from this empirical testing will inform FDA regarding likely population-level consequences. Because this notion is speculative, we propose testing it at the population level using a longitudinal survey of ECIG users and outcomes such as adverse health consequences, product consumption, dependence, and product switching. To the extent that population-level data support predictions generated by controlled testing, FDA will have at its disposal a model that can be used to shape, refine, and predict the effects of potential regulatory action.

B. Overall Rationale. This effort will provide a transdisciplinary model with which empirical data from several domains can help FDA to predict the extent to which potential tobacco product regulation is likely to meet the mandated "public health standard". As discussed, this standard requires FDA to consider how regulation will influence the risks and benefits to tobacco product users and non-users. We argue that this consideration of risks and benefits is best done prior to regulation taking effect, and is best informed by rigorous science that includes testing of product toxicity, user behavior and behavioral economic indicators of abuse liability. We have mentioned one case where regulation took effect without informative empirical data: labeling of cigarette packs with "tar" and nicotine yields. In this case, unintended consequences (product switching instead of cessation) and subsequent harm are well-documented (NCI, 2001). The model we propose offers a mechanism with which FDA can ensure future regulation has the health-promoting consequences that are intended and not harmful ones that are unintended. In addition to meeting the scientific goal of testing the