Title: Effects of E-Cigarette Power and Nicotine Content in Dual Users and Vapers

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ID: HM20012696 View: SF - Study Identification

HM20012696 - Caroline Amey
Effects of E-Cigarette Power and Nicotine Content in Dual Users and Vapers

Study Identification

1. * **Select the Principal Investigator:**
   Caroline Amey
2. * **Study Title:**
   Effects of E-Cigarette Power and Nicotine Content in Dual Users and Vapers
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. **If this is associated with other VCU IRB protocols or a resubmission of a withdrawn/closed protocol, select the VCU IRB numbers assigned to those studies:**

ID	Title	PI
HM20002567	CBTB Overall Screening and Registry	Alison Breland
HM20007677	Behavioral Health Research Laboratory Screening and Registry	Caroline 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	cdlloyd@vcu.edu	8048288687	
Barnes	Andrew	abarnes3@vcu.edu		
Breland	Alison	abbrelan@vcu.edu	8046282300	
Eissenberg	Thomas	teissenb@vcu.edu	8048274617	
Kilgalen	Barbara	bkilgalen@vcu.edu	8048273562	
Lester Scholtes	Rebecca	lesterrc@vcu.edu		
Underwood	Megan	underwoodml@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. Also check Yes if the study does not involve a test article but intends to provide safety or efficacy data to the FDA about an FDA regulated product.

   ○ Yes ● **No**

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

   ○ Yes

   ● **No**

3. * **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

   ☑ **None of the above**

IRB Panel Setup

1. * **To which IRB is this study being submitted for review?**

   ● **VCU IRB**

   ○ Western IRB

   ○ NCI Central IRB

   ○ Other IRB

2. * **Does this protocol already have a VCU IRB study number (HM number) and is being submitted as a new study in order to transition to review by another IRB?**

   ○ Yes - transitioning from VCU IRB to an external IRB (WIRB, CIRB, Other)

   ○ Yes - transitioning from an external IRB (WIRB, CIRB, Other) to VCU IRB

   ● **No or not applicable**

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. * **Does this study involve greater than minimal risk:**

   Does this study involve greater than minimal risk:

○ Yes

● **No**

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

ID: HM20012696 View: SF2 - Initial Setup Complete

Initial Setup Complete

Protocol Progress:
① **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

ID: HM20012696 View: SF2 - Background, Rationale and Goals

Background, Rationale and Goals

1. * **Describe the study's background and significance, 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 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 exclusive ECIG users and dual users of ECIGs and tobacco cigarettes (ECIG+TCig users), it may learn much from robust scientific methods that predict the likely population-level impact of potential regulatory action in these populations. To understand the benefit of predicting regulatory impact, consider the European Union's (EU's) directive (2014/40/EU) that limits ECIG liquids to <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…" This directive does not account for variability in product characteristics that work against its intent and may increase public health risk. Consider device power: early ECIGs were powered at 10 W or less, but current models achieve 150 W or more. Ten puffs from high power ECIGs (mean=70 W) filled with low nicotine concentration liquid (mean=4 mg/ml) can meet and sometimes exceed the nicotine delivery of a tobacco cigarette (Wagener et al., 2017).

   Use of these "third generation" ECIGs is rising (e.g., Barrington-Trimis et al., 2017) and, relative to lower power devices, they can produce more carcinogens (Gillman et al., 2016; El-Hellani et al., 2016) and lead users to consume more liquid (e.g., Wagener et al., 2017; Etter, 2016a). These results suggest that, when higher power devices are available, the intended consequences of the EU directive are less likely to be realized and unintended consequences (more liquid consumed) are more likely to occur. The ability to predict the effects of regulatory action might help FDA craft polices that are more likely to meet their intent while limiting unintended consequences. 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 with this study is to provide these methods to FDA. To do so, we use behavioral economic indices of abuse liability to examine the effects of limiting device power and nicotine concentration.

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 differences in electronic cigarette (ECIG) nicotine concentration and device settings (voltage and resistance settings, which determine's the devices power level) among groups of Dual Users (tobacco cigarette and ECIG users) and ECIG exclusive users.

We hypothesize that as nicotine concentration is lowered, abuse liability indices will be lowered, as assessed by less willingness to pay/work for ECIG puffs and more price sensitivity, but that these effects will be offset by higher power. Also, relative to dual ECIG+TCig users, exclusive ECIG users will exhibit larger reductions in abuse liability at lower nicotine concentrations. This pattern highlights how limiting liquid nicotine alone may not alter overall ECIG abuse liability in markets where higher power devices allow nicotine intake to be maintained.

3. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
The aims of this study are to better understand how power settings of electronic cigarettes (ECIGs) combined with liquids of differing nicotine concentrations impact several measures of abuse liability.

Results will be used to inform future tobacco product regulations of these device features/characteristics.

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 device features/characteristics as well as provide information to guide appropriate regulation of ECIGs. We anticipate long term benefits to the public at large by adding to the limited body of knowledge involving these devices among ECIG only users and dual cigarette and ECIG users.

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

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

ID: HM20012696 View: SF2 - Study Population

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.
300

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

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:**
120 completers (60 ECIG exclusive users and 60 Dual ECIG and Tobacco Cigarette users) are required to achieve greater than 80% given p= <0.05 for the breakpointMCP and breakpointPRT. We excluded own brand controls to ensure we are powered to detect differences across experimental conditions.

We estimate up to 300 individuals may be consented over the course of the study. Please note that initial telephone/web screening is performed under separate protocols - HM20007677 and HM20002567.

4. * **List the study inclusion criteria:**
General Inclusion:
Age 21 – 55 (verified by photo ID), willing to provide informed consent, they must agree to attend the lab and abstain from tobacco/nicotine as required and able to provide a semi-quantitative urine cotinine result of 'positive' at screening.

ECIG exclusive Inclusion:
Reports using >=1 ml of ECIG liquid/day or approximately one pod/cartomizer per day of at least 3 mg/ml nicotine for the past 3 months or longer and no tobacco cigarette consumption within the past 30 days.

Dual ECIG and Tobacco Cigarette User Inclusion:
Reports daily use of ECIGS (≥ 3 mg/ml nicotine) or tobacco cigarettes (any frequency) AND someday use (≥ 3 days per week) of ECIGs (≥ 3 mg/ml nicotine) or tobacco cigarettes (any frequency) for the past 3 months or longer.

5. * **List the study exclusion criteria:**
Individuals with the following self-reported current, diagnosed medical condition(s) will be excluded automatically: 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. Participants with any medical condition/medication that may affect participant safety, study outcomes, or biomarker data will be excluded based on these consultations.

Participants with self-reported current, diagnosed psychiatric conditions or who report current psychiatric treatment or psychotropic medication use will be excluded.

Individuals with past month use of cocaine, opioids, benzodiazepines, methamphetamine, or other illicit drugs. Self-report of >15 days out of the past 30 for marijuana use, or >25 days out of the past 30 for alcohol use.

Individuals who report using any other tobacco products on a weekly or more frequent basis will be excluded.

Women who are breast-feeding or test positive for pregnancy (by urinalysis at screening) will be excluded.

Individuals intending to quit tobacco/nicotine products in the next 30 days will also be excluded and referred to tobacco cessation treatment.

In addition, participants who have previously participated in a study with exactly the same manipulations of ECIG type, setting, and liquid nicotine concentration will be excluded. Individuals enrolled in HM20012738 will be excluded from the current study. Staff from this protocol will work with staff (who are also listed on this protocol) to assure that there is no cross participation between studies.

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 (<21 years old) from this study as asking them to use tobacco/nicotine products is illegal in Virginia. We also exclude pregnant/breastfeeding women 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 and/or tobacco/nicotine abstinence. 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.

ID: HM20012696 View: SF2 - Background, Rationale & Goals Section Complete

Background, Rationale & Goals Section Complete

Protocol Progress:
① **INITIAL SETUP**
② **BACKGROUND, RATIONALE & GOALS**
③ RESEARCH PLAN
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⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
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Click Continue below to go to the next section

ID: HM20012696 View: SF2 - Study Procedures

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 differences in electronic cigarette (ECIG) nicotine concentration and device settings (voltage and resistance settings, which determine's the devices power level) among groups of Dual Users (tobacco cigarette and ECIG users) and ECIG exclusive users.

   We hypothesize that as nicotine concentration is lowered, abuse liability indices will be lowered, as assessed by less willingness to pay/work for ECIG puffs and more price sensitivity, but that these effects will be offset by higher power. Also, relative to dual ECIG+TCig users, exclusive ECIG users will exhibit larger reductions in abuse liability at lower nicotine concentrations. This pattern highlights how limiting liquid nicotine alone may not alter overall ECIG abuse liability in markets where higher power devices allow nicotine intake to be maintained.

2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
   The aims of this study are to better understand how power settings of electronic cigarettes (ECIGs) combined with liquids of differing nicotine concentrations impact several measures of abuse liability.

Results will be used to inform future tobacco product regulations of these device features/characteristics.

3. * **Will the investigator obtain information or biospecimens for the purpose of screening, recruiting or determining the eligibility of prospective subjects?**
   - (●) **The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative.**
   - ( ) The investigator will obtain identifiable private information by accessing records.
   - ( ) The investigator will obtain identifiable biospecimens by accessing stored identifiable biospecimens.
   - ( ) None of the above

4. * **Choose all types of recruitment materials that may be used:**
   - [x] **E-mail invitations**
   - [ ] Phone Solicitation scripts
   - [x] **Flyers, Mailed Letters or Newspaper/TV/Radio Ads**
   - [ ] TelegRAM announcements
   - [x] **Website text**
   - [ ] Study-specific web sites (design and text)
   - [x] **Social Media**
   - [x] **Psychology Research Participant Pool (SONA) study descriptions**
   - [x] **VCU TelegRAM announcement**
   - [ ] Scripts for announcements made to groups
   - [ ] Other recruitment material
   - [ ] No recruitment materials

5. * **Provide a description of**
   1. How potential participants or secondary data/specimens of interest will be identified and
   2. All procedures that will be followed to carry out recruitment and screening activities (if applicable).

   Include details (as applicable) about:
   - How secondary data/specimens that meet the study's eligibility criteria will be identified (i.e. what database (s) will be queried and the search terms that will be used)
   - How potential participants will be identified and their contact information obtained
   - The timing and frequency of recruitment activities
   - Where and how recruitment procedures will be completed
   - Who will recruit or respond to potential participants
   - What and how written or verbal recruitment materials and reminders (if any) will be used
   - What screening activities will occur and how these procedures will be performed
   See the help text for additional guidance.

   Flyers will be posted around VCU (e.g., public poster boards in classroom buildings, dorms), on community message boards, laundromats, convenience stores, libraries. Websites used for recruitment will include the VCU Telegram, facebook, twitter, and craiglist. The social media advertisements will be posted on the VCU Behavioral Health Research Laboratory facebook page and posts and screenshots will be sent to IRB prior to posting for approval. An emailed advertisement may be distributed to VCU undergraduate classes with instructor permission or to VCU students involved with greek life at VCU via email by contacting the presidents of VCU fraternities/sororities. Each class or fraternity/sorority will be emailed no more than 2 times per semester. It will not be possible for students to opt out of these emails, as they will be sent via list serves through instructors of courses or presidents of VCU fraternities/sororities, which utilize their list serves to send important information to their associated students and/or members. The same email will be sent each time (please see attached email advertisement).

   All of these advertisements direct participants to the phone number used for our registry (HM20002567 or HM20007677) but the advertisements themselves are specific to this study (HM20012696).

   Interested individuals will respond to recruitment materials by visiting the screener survey/registry webpage (HM20002567 or HM20007677) or calling a dedicated study line answered by HM20002567/HM20007677 staff for screening. The informed consent document posted on the webpage is either read by the participant directly (online) or read verbally by HM20002567/HM20007677 staff. After participants agree to either an eligibility screening online or over the telephone (using the identical survey), the screening questions will be completed/asked. Individuals may also consent to join the research registry as part of HM20002567/HM20007677. As part of HM20002567/HM20007677, information is described about the current study during consent. Study staff will evaluate eligibility for individuals who consent to the screening for all studies that are described in HM20002567/HM20007677. If potentially eligible, staff on HM20002567/HM20007677 will notify staff of HM20012696 with name and contact information for these individuals. Staff on HM20012696 will not able to see any screening information other than name and contact information and eligibility status. Eligible individuals from the screener will be scheduled by telephone or email by HM20002567/HM20007677 staff for an in-person informed consent/screening appointment (see scripts).

6. * **Is a separate protocol document being uploaded that contains a detailed description of the study's methodology and procedures?**

   ○ Yes

   ● **No**

7. * **If 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. A description of all research measures/tests/interventions that will be used (if applicable)
4. A detailed description or list of all secondary data elements and/or secondary specimens that will be obtained and how they will be used (if applicable)
See the help text for additional guidance

Overview. This study involves 60 current E-Cigarette (ECIG) only users and 60 Dual Users (ECIG + traditional tobacco cigarette) who will complete 5, within-subject, laboratory conditions that differ by the product used: 1) ECIG with low mg/ml; low watts, 2) ECIG with low mg/ml; high watts, 3) ECIG with high mg/ml; low watts, 4) ECIG with high mg/ml; high watts, and 5) own brand (ECIG or tobacco cigarette). The first ECIG 4 conditions will be Latin-square ordered and single blinded such that the participants will not know which condition is administered in each ECIG session. The last condition for all subjects will be their own brand. For ECIG users it will be their own brand ECIG. For Dual Users it will be either own brand ECIG or tobacco cigarette. To allow for comparisons between groups (ECIG vs Dual) for this own brand condition, we will aim for a majority of the Dual User sample to receive their own brand ECIG in the last session.

Participants. A total of 120 adults (ages 21-55) who currently use ECIGs only or dual ECIG and tobacco cigarettes will be enrolled. We will attempt to recruit an equal number of men and women of diverse racial/ethnic backgrounds, although this study is not intended to address gender or race/ethnic differences.

Inclusion criteria: To be included, participants must be healthy, as determined by self-report and heart rate/blood pressure (HR/BP) check, between the ages of 21-55 (as verified by photo ID), and willing to provide informed consent. They must agree to attend the lab and abstain from tobacco/nicotine as required, to use the designated products, and to follow the study protocol.

Participants must also be either A) ECIG only users [reports using >=1 ml of ECIG liquid/day or approximately 1 pod/cartomizer/day of at least 3 mg/ml nicotine for the past 3 months or longer and no tobacco cigarette consumption within the past month] or B) Dual ECIG + traditional tobacco cigarette smokers [reports daily use of ECIG (≥ 3 mg/ml nicotine) or tobacco cigarettes (any frequency) AND some day use (≥ 3 days per week) of ECIGs (≥ 3 mg/ml nicotine) or tobacco cigarettes (any frequency)] use for the past 3 months or longer] who can provide a semi-quantitative urine cotinine result of 'positive' at screening (urine cotinine cassette test).

Exclusion criteria: Individuals with the following self-reported current, diagnosed medical condition(s) will be excluded automatically: 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. Participants with any medical condition/medication that may affect participant safety, study outcomes, or biomarker data will be excluded based on these consultations. Participants with self-reported current, diagnosed psychiatric conditions or who report current psychiatric treatment or psychotropic medication use will be excluded. Individuals with past month use of cocaine, opioids, benzodiazepines, methamphetamine, or other illicit drugs will be excluded as well as those who self-report of >15 days out of the past 30 for marijuana use, or >25 days out of the past 30 for alcohol use. Individuals who report using any other tobacco products on a weekly or more frequent basis will be excluded. Women who are breast-feeding or test positive for pregnancy (by urinalysis at screening) will be excluded. Those who intend to quit tobacco/nicotine products in the next 30 days will also be excluded and referred to tobacco cessation treatment. Individuals enrolled in HM20012738 will be excluded from the current study.

Recruitment and Enrollment. Potential participants will be recruited by IRB-approved advertisements, as well as referral from current participants. Once initial screening is completed (either over the phone or via the internet), potentially eligible participants will earn $10 to come to the lab for in-person informed consent, screening, and familiarization with study procedures (approximately 1.5 hrs). Prior to in-person data collection, staff will review the informed consent with potential participants to ensure they understand the study, its risks and benefits, and their rights as research participants. Following documentation of informed consent, participants will complete baseline measures to confirm eligibility and provide a urine sample that will be tested for cotinine level (to confirm current smoking status) and pregnancy (women only). Age will be verified by asking participants to provide some form of identification that includes a date of birth. We will also take pictures of their device/liquid. All study procedures will be reviewed and participants will be asked to choose the ECIG liquid flavor to be used during the four study ECIG sessions (i.e., not their own brand session). They will be given the opportunity to test four ECIG liquid flavors using the study ECIG device (tobacco, menthol, dessert, fruit) during screening. After flavor testing, participants will complete the Balloon Analogue Risk Task (BART) and the Minute Discounting Task (counter-balanced administration). Depending upon task performance, participants will receive up to $40 in compensation for the actual amount earned at the end of the BART task.

New recruits will replace participants who do not complete the study. Accrual ends when the required number of completers (N=120) is reached.

Products. Own brand tobacco cigarette packs or ECIG liquids consistent with participant preference will be purchased locally following enrollment. For all other sessions we will provide ECIG liquid at 10mg or 30 mg nicotine and an “open system” ECIG (i.e., Kanger Sub Box Mini C) set to either 15 watts or 30 watts. Liquid flavors available will include tobacco, menthol, dessert, and fruit.

Procedure. For each session, participants will be asked to refrain from tobacco/nicotine use for ≥12 hours and eating food/drinking caffeinated beverages for 1 hour prior to their scheduled session with verification of tobacco/nicotine use status upon arrival at the lab (expired air CO ≤7 for ECIG users and ≤10 ppm for Dual Users). At the start of the

session, participants rest for 30 minutes, at this time participants will be asked about symptoms experienced since last visit.. During this time, participants will not be allowed to use their phones, eat or drink outside beverages but we will provide water to drink and they are invited to read books/magazines or watch movies that we provide to them. Thirty minutes (min) after session onset, participants will sample the session-specific product (2 puffs) followed by a 1 hour rest period, following the same guidelines as the first 30-minute rest period. After the rest period, baseline subjective measures to assess tobacco abstinence symptoms will be completed. Immediately after either the PRT or the DPT/MCP tasks will be completed. The PRT takes approximately 40 minutes to complete and the DPT/MCP takes approximately 40 minutes to complete. Please note that this order, PRT – DPT/MCP or DPT/MCP – PRT, is counterbalanced across participants to control for the effects of completing one task set prior to the other. Following the 1st counterbalanced task assessment, participants will complete a 60-minute rest period. The study procedures should take no more than 240 minutes or 4 hours but study procedures could be completed earlier than that based on decisions the participant makes during the PRT.

0m – CO Check; Physio data collection begins, additional questions about symptoms asked.
30m – 2 puff sample
90m – CO Check; Subjectives measure 1
100m – DPT/MCP OR PRT
140m – Behavioral Measure 1 completed
Subjectives measure 2
Begin 60m rest period
200m – Subjectives measure 3
DPT/MCP OR PRT
240m – Behavioral Measure 2 completed
Subjectives measure 4
end session

Product administration will consist of a 2 sample puff at the beginning of each session. Three behavioral choice tasks will be performed (DPT, MCP, and the PRT). Two of those, (The MCP and the PRT) may yield additional puffs, depending on the decisions made. See the Behavioral Measures section below for more details.

Measures.

Baseline measures. During the in-person eligibility screening, we will assess sociodemographic information, risk taking/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. We will also take pictures of participant devices and preferred e-liquid. We will also be obtaining baseline physiological measures including: expired air CO and HR/BP. CO 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).

Risk tasking and discounting tasks will only be administered to participants at baseline who appear eligible based on all the criteria assessed during the in-person screening. These two tasks will be the final assessments for participant who appear to be eligible at the in-person screening.

The Balloon Analogue Ratio Task (BART) is a risk taking behavior measure that presents a computerized balloon that continuously expands with each click of a button. Each time the balloon inflates, the amount of money that the participant can earn incrementally increases as well. Each balloon has a set explosion threshold (amount of clicks it takes to pop), which is unknown to the participant. Each pump increases the potential earnings by 5 cents. With every additional pump, the risk of explosion increases, as well as the amount of potential earnings. If the participant chooses to accept the earnings prior to the explosion, then it is added to their total earnings for the entire set of balloon trials, but if the balloon explodes prior to the collection of earnings, then those earnings are lost for that trial. Participants will complete 20 trials (20 balloons) and receive the accrued earnings upon the completion of all trials. Initial testing suggests earnings may average approximately $35 per participant. A maximum of $50 will be dispensed from the earnings from this task.

The Minute Discounting Task is a series of hypothetical decision scenarios. Each scenario presents a choice between receiving an amount of money in the present moment or an amount of money at a later time period. These choices are differentiated by option amounts and the time frames. 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. This task will only be administered once, during the in person screening.

Physiological measures. Physiological measures are being collected primarily for participant safety during sessions. 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 three behavioral choice tasks (Progressive Ratio Task, Drug Purchase Task, and Multiple Choice Procedure).

The Progressive Ratio Task (PRT) requires participants to click on a button on a computer screen 4 times to earn 1 puff of the session specific ECIG. With each additional puff the PRT requires the participant to ‘work’ twice as hard, in other words after each reward (a single puff) the participant will be required to press the button 8 times, 16 times, 32 times, et cetera for each successive puff. Once the participant declines to press the button for five minutes then the PRT is considered complete.

The Drug Purchase Task (DPT) includes 9 unique measures that assess hypothetical tobacco product purchasing behaviors that are specific to each population (exclusive ECIG user and Dual users) and differ by the session type (experimental ECIG or own brand session). Please see Drug Purchase Task Overview within the attached document. Exclusive users complete 2 or 3 measures for the DPT during each session. Dual users complete 3 or 5 measures for the DPT during each session. DPT measures assess single product purchasing behavior for the session specific ECIG and own brand ECIG/cigarette (1-4; Drug Purchase Task Overview) as well as cross product purchasing behavior between these three products (5-9; Drug Purchase Task Overview) at varying amounts of money. ($0-$10.24)

Importantly these tasks are programmed to end early if participants report zero consumption for assessed products. Estimated time per measure is <3 min, and each measure will only be completed once per session.

The Multiple Choice Procedure (MCP) questionnaire consists of three columns and 15 rows. Ten puffs from the session specific product (session specific ECIG or Own Brand ECIG/Cigarette) will be shown in the center column while varying amounts of money ($0.01 - $10.24) will be presented in ascending order in right column. Participants will be instructed to circle whether they prefer puffs or money for each of the 15 choices given to them. The MCP will only be administered once, immediately following the DPT. Immediately after the questionnaire is completed, participants will be presented with one of their choices (drawn randomly) and given a 10-minute 'consumption' period in which to take puffs or receive money. After the consumption period, participants will rest for 10 minutes before either ending the session or beginning the 60-minute rest period.

Subjective measures. Repeatedly within each condition we will use the Minnesota Nicotine Withdrawal Scale and the Direct Effects of Nicotine Scale to measure nicotine withdrawal symptoms before and after each behavioral measure.

Data analysis. Subjective, physiological, DPT, MCP, and PRT data will be prepared as reported elsewhere (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 (some differences are expected, like cigarette use). Unexpected between group differences will be considered as potential covariates in the primary analysis (see Evans et al., 2006). For all ANOVAs, adjustments for sphericity violations and post-hoc testing using Tukey's HSD or planned contrasts with Bonferroni corrections will be used (Keppel, 1991). Missing data will be imputed using multiple imputation techniques (Allison, 2001).

8. * **The IRB only reviews research procedures, so differentiate which of the study procedures are:**

   a. Being performed exclusively for research purposes (i.e. they would not otherwise be done apart from this study).
   b. Alterations of routine procedures (e.g. the study is altering the timing, frequency, method, location, amount, etc.).
   c. 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.).
   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:**

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:

Project Details

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)**
   - [ ] Placebos
   - [ ] Safety and/or effectiveness evaluation of Bio-Medical Device(s), including in-vitro diagnostic devices/assays, mobile medical apps, 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 that apply to this study (selections will branch):**
   - [ ] Passive Internet data collection (i.e. passively observing online behavior)

- [x] **Active Internet data collection (i.e. using the internet to interact or intervene directly with research participants)**
- [ ] Audio / Video recording or photographing participants
- [ ] Observations
- [ ] Educational Settings/Assessments/Procedures
- [ ] Interviews / Focus Groups / Verbal responses to questions
- [x] **Surveys / Questionnaires /Written responses to questions (including data entry)**
- [ ] None of the Above

3. * **Select all types of secondary information and/or specimens that apply to this study (selections will branch): See the help text for definitions.**
   - [ ] Protected Health Information (PHI)
   - [ ] Secondary data/specimens NOT from a research registry or repository
   - [x] **Information/specimens from a research registry or repository (Usage Protocol)**
   - [ ] 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 Details

1. * **Describe the duration of the social/behavioral intervention:**
   Five sessions that are 4 hours long each.
2. * **Describe any potential harms or discomforts that participants could experience during the intervention:**
   From the consent form:

   1. You may experience some mild discomfort during the 12-hour tobacco/nicotine abstinence period before each session. Side effects from tobacco/nicotine abstinence can include irritability, anxiety, restlessness, excessive hunger, difficulty concentrating, and sleep disturbance. Though uncomfortable, these feelings are not medically dangerous.

   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 more nicotine than you usually use, although some e-cigarette users report using these liquids. Inform the study staff immediately if you experience any discomfort.

   4. 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/e-cigarettes regularly.

   5. 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.

   6. In many 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, and the Centers for Disease Control and Prevention has advised people to stop vaping. In some cases, symptoms of mild to moderate gastrointestinal illness such as nausea, abdominal pain, vomiting, diarrhea, or fevers or fatigue have been reported. 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.

   7. 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.

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

   9. E-cigarette devices will be reused for participants. New disposable mouthpieces will be provided to each participant. There is some risk of contamination or illness, which is minimized by sanitizing the e-cigarette devices in addition to the use of these mouthpieces.

   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 be physically invasive or painful?**
   - ○ Yes
   - ● **No**

4. * **Describe the impact the intervention will have on participants, including the nature and duration of any impact(s):**
   Participants will be using an ECIG and/or an own brand 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 ECIG users or dual (ECIG and cigarette) users.

5. * **In the investigator's opinion, is there any reason to think that the participants will find the intervention 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	Nicotine-containing electronic cigarette liquid (10 and 30 mg nicotine) in tobacco, menthol, dessert, and fruit flavors	AVAIL Inc	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	Own brand electronic cigarette liquid	Various Manufacturers	Other (Drug or Compound Not Listed Above)	Not Applicable	Not Required	

2. * **Will the Investigational Drug Service (IDS) pharmacy be utilized:**
   - ○ Yes
   - ○ No (upload approval of the IDSP management plan below)
   - ● **Not Applicable**

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

   B1. For drug products that require an IND, upload at least one of the following documents for verification of the IND number:
   - External sponsor's protocol including IND number and signed Form FDA 1572 for the VCU Principal Investigator
   - Communication from the external sponsor verifying the IND number and 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 documents for each applicable drug:
   - A document explaining, with protocol-specific information, how the drug's use in this study meets the relevant critieria 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. If the Investigational Drug Service Pharmacy (IDSP) is not utilized, upload the IDSP management plan approval.

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**
   - [x] **Other**
   - [ ] None of the Above

2. * **If Other, please describe the type of sample being collected:**
   Expired air carbon monoxide will be assessed at the start of the session and again 90 minutes into the session. No sample will be saved.

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

4. * **Describe how the samples 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

   Urine will be collected during the baseline screening to test for recent nicotine exposure and for current pregnancy for women. At least 30 mL is required for testing purposes, participants may provide more but it isn't required. Please note no urine is saved. 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 the urine sample is disposed of via toilet and the urine collection cup is disposed of in the garbage.

5. * **Will genetic testing or 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. Give the rationale for selecting this technology.**
   Screening, baseline, and session data will be collected and stored using the REDCap database (when applicable) which is located on a category one secured database at VCU.

2. * **Describe how data will be linked or unlinked to identifiers including email addresses, names, and/or IP address.**
   Phone/Web screening data are kept in a separate REDCap project file and will be linked to participants names, phone numbers, and email addresses. This data is collected under protocol HM20002567/HM20007677. Only contact information and participant names are given to staff under the current protocol.

   Consent documents are given a unique identifier. Baseline and session data are identified by numeric code only and stored in a separate REDCap project from the screening data. This 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).

   All electronic records will be made available only to those personnel in the study through the use of access controls and encryption.

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

4. * **If yes, describe the alternative(s).**
   Participants can call and complete the Phone/Web screening survey (HM20002567/HM20007677) over the telephone with a member of the research staff. Their answers will be collected using the same online survey form.

   Other study forms can be completed on paper if necessary during in-person assessments.

5. * **Describe how individuals will be able to skip or not answer particular questions. If any questions are mandatory, provide justification.**
   Participants can skip any question except for the initial consent question to complete the Phone/Web screening survey: "Are you ready to start the questions?" (yes/no) and age.

   Participants can skip other questions administered during the baseline session except for those required for eligibility purposes.

6. **If not including children, describe any procedures used to verify that research participants are adults.**
   The REDCap screening survey will automatically end for any individuals who indicate they are <18 years old. In-person screening also ends immediately if an individuals identifies as <18 years old.

Secondary Data/Specimen Details

1. * **Describe the source and nature of the information/specimens being obtained.**

   Provide information about:
   1. where will the data/specimens come from (e.g., another researchers registry, pathology lab, commercial source, etc.
   2. what type of data/specimens will be obtained
   3. a list of all data elements that will be obtained (a data collection form or other documentation may be uploaded and referenced here)
   CSTP Overall Screening and Registry and the Behavioral Health Research Laboratory Screening and Registry surveys include self-reported information including contact information, demographics, health, and use of tobacco, alcohol, and other drugs.

   Data from these items are primarily used to evaluate potential eligibility of participants for the current protocol by staff on HM20002567/HM20007677. For screening purposes, only participant name and contact information and eligibility status will be provided to staff on HM20012696 (available for all participants who complete the survey and not necessarily agree to the registry).

2. * **Describe how you will be granted access to the information/specimens**
   Staff on this protocol (HM20012696) will request access to data by staff on protocols HM20002567/HM20007677.

   HM20012696 staff will be added as staff on HM20002567/HM20007677. Once this has been IRB approved staff will be given access to the REDCap project and relevant data. REDCap reports will be processed to identify potentially eligible participants for HM20012696.

3. * **Describe any identifiers or coded information that will be obtained that can be linked directly or indirectly to the identity of participants.**

   Provide information about:
   1. the associated identifiers, or how a code has been assigned
   2. whether or not you will be granted access to the ability to re-identify participants
   3. whether an agreement is in place between you and the provider indicating you will never have access to the ability to identify the participants
   For screening purposes, only participant name and contact information and eligibility status will be provided to HM20012696.

4. * **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

5. **If Yes, did the original research consent document allow for sharing of the data the information/specimens to be shared for the specific area of study that is proposed by this research?**
   - (●) **Yes**
   - ( ) No

6. * **Provide name(s) of the registry/repository being accessed, if applicable.**
   CSTP Overall Screening and Registry

Behavioral Health Research Laboratory Screening and Registry

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

8. **Describe the Non-VCU organization and/or individual responsible for management and control of the registry / repository.**

9. **If the registry / repository is located at VCU, provide the IRB number for the registry / repository.**
   HM20002567; HM20007677

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

11. **If NO above, describe in detail the allowed uses of the data information/specimens as outlined in the registry / repository consent. Be sure to describe any stipulations or limitations on the use.**

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

ID: HM20012696 View: SF2 - Costs to Participants

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

2. * **Provide details of all financial costs to the participant, other than time and transportation. Additional details regarding standard of care costs will be requested on another screen, if applicable.**
   None.

ID: HM20012696 View: SF2 - Compensation

Compensation

1. * **Describe any compensation that will be provided including:**
   1. total monetary amount
   2. type (e.g., gift card, cash, check, merchandise, drawing, extra class credit)
   3. how it will be disbursed
   Eligible and Ineligible participants will be paid $10 after the in-person screening. Eligible participants will be paid for their responses/in cash at the completion of the in-person screen (based on their performance of the BART task) and for each of five sessions.

   If lab parking is not available you will be reimbursed for parking expenses only.

2. **If compensation will be pro-rated, explain the payment schedule.**
   Eligible and Ineligible participants will be paid $10 after the in-person screening. Eligible participants will be allowed to perform the BART task and may receive up to $40 based on their performance of this task (see Research Description for greater detail).

   If enrolled, compensation will be $75 for session 1, $100 for session 2, $100 for session 3, $100 for session 4, and $125 for session 5 for a total potential compensation of $500.

   In each session, participants may earn between $0 to $10.24 depending on the choices they make in the multiple choice procedure task.

   Additionally if lab parking is not available for In Person Screen or Study Sessions participants will be reimbursed for parking expenses only.

3. * **Will Social Security Numbers be collected for compensation purposes only?**
   - (●) **Yes**
   - ( ) No

ID: HM20012696 View: SF2 - Research Plan Complete

Research Complete

Protocol Progress:
❶ **INITIAL SETUP**
❷ **BACKGROUND, RATIONALE & GOALS**
❸ **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

ID: HM20012696 View: SF2 - Consent Process

Consent Process

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

	Group	Types	Waivers	Roles	Roles - Other	Consent	Coercion	Decision	Re-Consent
View	In-person consent	Written/Signed Consent by Participant	No Waivers Requested	Principal Investigator Co/Sub-Investigator Research Coordinator Research Assistant Trainee/Student (i.e. not Student-Investigator)		In a private room located at the Center for the Study of Tobacco Products (CSTP) or Behavioral Health Research Lab (BHRL).	Participants are read the consent form aloud and encouraged to ask questions before signing.	As much time as necessary.	

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

ID: HM20012696 View: SF2 - Consent Plan Complete

Consent Plan Complete

Protocol Progress:
❶ **INITIAL SETUP**
❷ **BACKGROUND, RATIONALE & GOALS**
❸ **RESEARCH PLAN**
❹ **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. Participants may experience some mild discomfort during the 12-hour tobacco/nicotine abstinence period before each session. Side effects from tobacco/nicotine abstinence can include irritability, anxiety, restlessness, excessive hunger, difficulty concentrating, and sleep disturbance. Though uncomfortable, these feelings are not medically dangerous.

   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.

   Other ECIG related side effects may include a sore or scratchy throat and headache. In addition, some people who use e-cigarettes have experienced seizures (https://www.fda.gov/tobacco-products/ctp-newsroom/some-e-cigarette-users-are-having-seizures-most-reports-involving-youth-and-young-adults). These have been reported among individuals with a history of seizures as well as among individuals using other substances such as marijuana and amphetamines, as well as among others. In addition, recently there have been many cases of e-cigarette use being associated with respiratory illnesses such as difficulties breathing, shortness of breath, cough and/or check pain before hospitalization. In some cases, e-cigarette use has led to death and the Centers for Disease Control and prevention has advised people to stop vaping. In some cases symptoms of mild to moderate gastrointestinal illness such as nausea, abdominal pain, vomiting, diarrhea or fevers or fatigue have been reported.

   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. The ECIG liquid used may contain more nicotine than participants normally use.

   These effects are unlikely in individuals who use e-cigarettes/cigarettes regularly.

   There is some risk of illness/contamination due to ECIGs being reused between participants.

   There is some risk of loss of confidentiality.

   In addition, recently (as of September 2019) there have been many cases of e-cigarette use being associated with respiratory illnesses such as difficulties breathing, shortness of breath and/or chest pain before hospitalization. In some cases, e-cigarette use has led to death, and the Centers for Disease Control and Prevention has advised people to stop vaping. In some cases symptoms of mild to moderate gastrointestinal illness such as vomiting, diarrhea, or fevers or fatigue have been reported.

2. * **Describe how each of the risks/harms/discomforts identified above will be minimized:**
   Tobacco/nicotine abstinence syndrome: As individuals entering this study may exhibit signs of nicotine dependence there is a possibility that during the 12-hour tobacco/nicotine abstinence period prior to each session, participants may experience symptoms associated with tobacco/nicotine abstinence including irritability, anxiety, restlessness, hunger, and difficulty sleeping. Importantly these effects can be uncomfortable but are not medically dangerous. Participants will be informed of these potential abstinence-related side effects during the informed consent.

   During the sessions, if the participant reports experiencing small droplets of ECIG liquid during inhalation, we will immediately replace the device he or she is using in the session.

   We will inform participants of the other ECIG-related side effects during the informed consent process.

   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 (10 puffs plus a 60 minute ad lib use period). 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.

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 a 4-hour session and the number of subjective and behavioral assessments per session are not worthy of noting as discomforting.

Though ECIGs will be reused every participant will receive a new disposable mouthpiece that is placed on the ECIG mouthend of the device at each session. Additionally the ECIGs will be cleaned between sessions with rubbing alcohol and water.

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.

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:**
   Individuals whose BP levels are elevated (>=140 mmHg systolic or >=90 mmHg diastolic) during baseline screening will be referred to a primary care provider.

   Research personnel are trained to alert the research nurse/medical monitor if heart rate exceeds 120 beats per minute, if systolic BP exceeds 150 mm Hg, or if diastolic BP exceeds 100 mm Hg. Individuals whose heart rate and/or BP levels remain elevated will be monitored continually 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 CBPL/CSTP or a half block away from the BHRL.

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/medical monitor/research nurse has any safety concerns (such as observation of high blood pressure; systolic BP>=140 or diastolic BP>=90) during baseline screening or continuous/repeated high blood pressure observations during study sessions.

   The PI/research nurse and/or Medical Monitor will be consulted/notified via phone/email specifically concerning high blood observations that occur during any study session to determine whether a participant should remain in the study.

   If participants do not comply with study protocol during one of their sessions they may be allowed to repeat that session once.

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

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.

1. * **Describe how the research team will protect participants' privacy throughout the course of the study. Address privacy in the context of the following research activities as applicable:**

   - Identification of potential participants or secondary data/specimens of interest
   - Recruitment and screening activities
   - The informed consent process
   - Conduct of the study procedures
   - Data dissemination

   See the help text for additional guidance.
   Participants' privacy and comfort will be addressed throughout the course of this study. During the intake process and sessions, participants will be seated in a private room. All study procedures will take place behind closed doors. 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 standards of confidentiality. Data are identified by numeric code only and stored under double lock. Participants' names are not directly linked to data. Briefly, a unique code is assigned to each participant when they provide informed consent. A 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). 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. Dr. Eissenberg's lab (Co-I) has used these procedures for over 15 years and has not had a single incident in which a participant's confidential information has been compromised.

   To protect research participants when data is disseminated we will share results in aggregate only, rather than individual level data.

Data Confidentiality and Storage

Confidentiality refers to the way private, identifiable information about a participant or defined community is maintained and shared.

1. * **Specify where this study's paper and electronic research data and/or physical specimens will be stored and how 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 BHRL/CSTP lab in a locked room with entry to the lab secured by a keypad and only accessed by authorized study personnel.

   Electronic records will be stored in REDCap made available only to those personnel in the study through the use of access controls and encryption (VCU File Locker). 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 in the BHRL/CSTP lab. All web-based surveys will have data secured via passwords. De-identified data will transferred via File Locker to secure School of Medicine servers and School of Psychology servers that are password protected for data cleaning and analysis.

   Some data (self-report, physiological and topography) 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).

   Pictures of participant devices/liquid will be stored on the Research Drive and backed up on secure datakeys that require a password (IronKey).

2. * **Who will have access to study data?**
   Only staff associated with the current study will have access to the study data (paper, electronic).

3. * **If research data that contains any of the 18 HIPAA identifiers will be released to person(s) or group(s) outside of the VCU study team, identify the data recipient(s) along with their institutional or organizational affiliation (s).**
   Not applicable.

4. * **Select all identifiers that will be collected 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 >89
   - [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#

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

6. * **If the study will code (i.e. de-identify) the research data by replacing subjects' names 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 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 additional guidance.

   Data are identified by numeric code only and stored under double lock. 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 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). 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. The key is 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.

Data Retention

1. * **Select all of the ways information obtained during pre-screening and/or screening will be handled for individuals who DO NOT qualify for the study:**
   - ☐ Immediately destroy the information
   - ☐ 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 the information
   - ☐ Other
   - ☐ N/A - study does not require screening procedures

2. * **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**

3. * **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

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. * **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
- ○ Yes - Plan to submit request for CoC and will amend study/ICF once status of request is known

3. * **Select the way(s) that individual-level information or biospecimens (including DNA) may be used by the VCU PI or VCU study team for other future research projects (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. You 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. You 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
(You 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

4. * **Select the way(s) the VCU PI/study team may share individual-level 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. You 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. You 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 (You will be asked more questions about this on a later page.)

- [ ] Will submit data to an NIH genomic data repository (You 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

5. * **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.)**

   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)

6. * **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

7. * **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

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

ID: HM20012696 View: SF2 - Pertinent and Incidental Findings

Pertinent and Incidental Findings

1. * **Is it likely investigators could discover a participant's previously unknown condition (e.g. disease, suicidal thoughts, wrong paternity, pregnancy, 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 any possible pertinent or incidental findings stemming from research-only procedures that may be of importance to a subject's health or well-being or which may relate to illegal or reportable activities.**
   During screening we assess blood pressure.

   During screening we assess if female participants are pregnant.

   During screening we ask questions about marijuana/cannabis use and other illicit drug use.

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

3. * **Explain what actions or procedures should research personnel take to handle such a discovery :**
   If a participant's blood pressure is high, research staff will advise the participant to talk to their own doctor and to get treatment.

   If a participant is pregnant, research staff will advise the participant to seek prenatal care.

   If a participant reports marijuana/cannabis use, although this is an illegal activity, the search staff will not take any actions. This study does have 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.

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 contact 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.
   Findings for blood pressure and pregnancy will be communicated to participants verbally 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 communicate this information and advise the participant to seek treatment.

   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 or now knowing about high blood pressure or pregnancy.

   Participants do not have the option of refusing communication about their blood pressure reading 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:
❶ **INITIAL SETUP**
❷ **BACKGROUND, RATIONALE & GOALS**
❸ **RESEARCH PLAN**
❹ **CONSENT PLAN**
❺ **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.

   If the research is aimed at involving a broader subject population and may incidentally includes a listed population, only check the box if the participant group will be 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**

ID: HM20012696 View: SF2 - Populations with Special Considerations Section Complete

Populations with Special Considerations Section Complete

Protocol Progress:
❶ **INITIAL SETUP**
❷ **BACKGROUND, RATIONALE & GOALS**
❸ **RESEARCH PLAN**
❹ **CONSENT PLAN**
❺ **RISKS, PRIVACY & CONFIDENTIALITY**
❻ **POPULATIONS WITH SPECIAL CONSIDERATIONS**
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

ID: HM20012696 View: SF2 - Study Funding

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. **Select all related proposals:**

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

5. **If the following conditions are ALL met, provide the index code where ORSP 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

6. * **Does the funder require the IRB to review this proposal for grant congruence?**
   - (●) **Yes**
   - ( ) No

7. **If grant congruence review is requested, upload the entire grant proposal (exclusive of budget and appendices).**

   If Industry was selected above, upload the OSP Subject Injury Language Memo or other documentation from OSP approving the consent form's subject injury language.

ID: HM20012696 View: SF2 - Types of Sites

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 Medical Center
   - [ ] VCU Monroe Park Campus
   - [ ] VCU Qatar
   - [x] **Other VCU Site**

2. * **Provide details regarding each VCU Site including:**
   - what clinics / facilities will be used
   - resources that are available for the conduct of this study
   Resources include personnel time, equipment, space, hospital beds, etc
   The Center for the Study of Tobacco Products (CSTP) is located at 100 West Franklin Street, Suite 200, Richmond, VA. The suite consists of 7,900 square feet of office and laboratory space. The lab space includes 7 session rooms with individual ventilation to the exterior of the building, a sample processing room, an equipment/product prep room, and an additional room that can be used as a waiting room, for screening visits, or for other study visits. Each session room contains a comfortable chair, a desk and computer (for subjective and behavioral assessments), and physiological monitoring equipment (heart rate, blood pressure). In addition, each session room door has a large glass window, so that staff who are observing participants may minimize the time they are in the room while participants smoke or use other tobacco products like e-cigarettes. Telephones are located in open areas outside of the session

rooms.

Dr. Cobb's Behavioral Health Research Laboratory will be located on the MCV campus of VCU in the basement of McGuire Hall, 1112 East Clay Street, Suite B-01, Richmond VA. This space encompasses 639 square feet which includes 3 private participant rooms. There is a receiving section attached to these rooms. This space also contains storage and biological specimen processing area with a sink. Each participant room contains a computer testing station with physiological/subjective effect measurement software and a physiological monitoring device. A bathroom is located within 30 feet of these participant rooms. The lab's proximity to MCV Emergency Room and its location on a major Richmond, VA bus line makes it an ideal venue for the proposed research.

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
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

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

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:

ID: HM20012696 View: SF2 - Personnel

Personnel

1. * **Indicate in the space below, list all VCU/VCUHS personnel who are key study personnel.**

Key personnel are defined as: Conflict of Interest investigators, including the PI and student investigator, medically/psychologically responsible investigator, and other personnel whose roles are essential to the conduct of the research.

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
View	Caroline 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		Experience - Research Education and/or Professional Preparation		yes

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
				Data Management Participant Identification Data Entry Study Design Data Coding Participant Recruitment Data Collection - Interviews/Surveys				
View	Rebecca Lester Scholtes	Research Coordinator Research Assistant		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		no
View	Cosima Hoetger	Research Assistant Trainee/Student (i.e. not Student-Investigator)		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 Education and/or Professional Preparation Student		no
View	Alyssa Rudy	Research Assistant Trainee/Student (i.e. not Student-Investigator)		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 Education and/or Professional Preparation Student		no
View	Thomas Eissenberg	Co/Sub-Investigator		Data Analysis Project Coordination Study Design		Experience - Research Experience - Related Skills		yes

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
						Education and/or Professional Preparation		
View	Rose Bono	Research Assistant Trainee/Student (i.e. not Student-Investigator)		Data Analysis Data Management Data Entry Data Coding Participant Recruitment		Experience - Research Education and/or Professional Preparation Student		no
View	Alison Breland	Other	Dr. Breland is the PI for a similar study. We will exclude participants who have participated in Dr. Breland's study and she will exclude participants who have participated in this study. Thus, Dr. Breland is on this protocol so that we can cross-check participants to ensure that a participant does not complete both similar studies.	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 Education and/or Professional Preparation		yes
View	Barbara Kilgalen	Research Nurse		Data Analysis Data Collection - Direct Observation Participant Consent Data Collection - Lab Data Management Participant Identification Data Entry Data Coding Participant Recruitment Clinical Services Data Collection - Interviews/Surveys		Experience - Research Experience - Clinical Education and/or Professional Preparation		no
View	Melanie Crabtree	Research Assistant		Data Analysis Data Collection - Direct Observation Participant Consent Data Collection - Lab Data Management Participant Identification Data Entry Data Coding Participant Recruitment		Experience - Research Education and/or Professional Preparation		no

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
				Data Collection - Interviews/Surveys				
View	Thokozeni Lipato	Medical or Psychological Responsible Investigator		Data Collection - Lab Data Entry Clinical Services Data Collection - Interviews/Surveys		Experience - Research Experience - Related Skills Education and/or Professional Preparation		yes
View	Augustus White	Research Assistant Trainee/Student (i.e. not Student-Investigator)		Data Analysis Data Collection - Direct Observation 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 Student Trainee		no
View	Megan Underwood	Research Assistant		Data Analysis 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		no
View	Alisha Eversole	Research Assistant Trainee/Student (i.e. not Student-Investigator)		Data Analysis 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
View	Sarah Maloney	Research Assistant		Data Analysis Data Collection - Direct Observation Participant Consent Data Collection - Lab Data Management Participant Identification Data Entry		Experience - Research Experience - Related Skills Education and/or Professional Preparation Student		no

Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
			Data Coding Participant Recruitment Data Collection - Interviews/Surveys				

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. * **Describe the process that will be used to ensure that all persons at all involved sites assisting with the research are adequately informed about the protocol and their research related duties and functions:**
The PI, Co-I, research coordinator, and research assistants will meet bi-weekly in person to ensure the study team is continually up to date on each member's role and the study protocol. Meeting agendas and minutes will be posted for team members online with access to these folders password protected. In between these meetings, the team will stay informed via email and phone if immediate communication is needed among team members.

   Communication with between laboratory staff and the PI/Medical Monitor occurs as soon as possible during and/or after any adverse event occurs.

   The PI and Medical Monitor are available by mobile phone, office phone, and email. These numbers are posted centrally in the laboratory.

4. **CV/Biosketch: (required for PI, Medically/Psychologically Responsible Investigators and Student/Trainee Investigators)**

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 interests 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 the engaged individual(s) with a related financial interest
- Brief description of the 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).

   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
- conflicts 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 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.

ID: HM20012696 View: SF2 - Other VCU Requirementsv2

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/compliance_program/research_coverage.htm

   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/clinical-trials/clinicaltrialsgov.html 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 there a community partner in this research study?**
      ○ 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. **General Data Protection Regulation (GDPR) Requirements**
   Contact the VCU Research Data Privacy Office with questions about GDPR requirements: https://research.vcu.edu/data_privacy

   1. * **Does this study involve the VCU site, or any sites under the VCU IRB's oversight, obtaining data in, or from, the European Economic Area? (see Help Text for list of countries included in the EEA)**
      - ○ 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.
      - ● **Category 1: all data that require breach notifications in the event of improper release, including all non-publicly available 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.
      - ○ Category 3: all non-proprietary data that is considered publicly available for unrestricted use and disclosure. Such information is available to all members of the University community and to all individuals and entities external to the University.

   2. * **I confirm use of the VCU Data Classification Tool in determining the data classification category selected in Question 1:**
      - ● **Yes**
      - ○ No

      .

7. **Massey Cancer Center Protocol Review and Monitoring Committee (PRMC)**
   For guidance, see https://www.massey.vcu.edu/research/protocol-review/

   1. * **Does this study target any of the following populations?**
      - cancer patients,
      - family members of cancer patients,
      - cancer healthcare providers, or
      - cancer prevention where cancer is integral to the research question
      - ○ Yes
      - ● **No**

8. **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**

9. **VCU Faculty-Held IND or IDE**
   For guidance, see **http://go.vcu.edu/indide**

10. **VCU Health System locations**

    1. * **Will research activities occur in patient care areas of the VCU Health System (including at CHoR, Community Memorial Hospital, VCU Medical Center and Massey Cancer Center)?**
       - ○ Yes
       - ● **No**

11. **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

12. **VCU Institutional Biosafety Committee (IBC)**
    To contact the Biosafety Office, call 804 828-6347 or extension 400-4984, or view their website at: https://research.vcu.edu/ibc

    1. * **Does this project involve the use of Bio-Hazardous Substances such as gene transfer, use of organisms or their products, biological toxins, and/or viruses?**
       - ( ) Yes
       - (●) **No**

    2. * **Does this project involve recombinant DNA (rDNA) and/or synthetic nucleic acids?**
       - ( ) Yes
       - (●) **No**

13. **VCU Radiation Safety Committee (RSC)**
    To contact the Radiation Safety Section, call 804 828-9131, or view their website at: https://research.vcu.edu/rsc

    1. * **Does this study involve radiation exposure and/or scans involving radiation (e.g.: PET, MRA, CT, DXA, nuclear medicine, etc.)?**
       - ( ) Yes
       - (●) **No**

14. **Virginia-Stem Cell Research Oversight (SCRO)**
    For guidance, contact the Office of Research Integrity and Ethics (ORIE) at: ORIE@vcu.edu

    1. * **Does this study involve stem cells?**
       - ( ) Yes
       - (●) **No**

15. **VCU Scientific Review Committee (SRC)**
    For guidance, see https://cctr.vcu.edu/support/study-participation-recruitment/scientific-review

    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:**

Institutional Requirements Complete

Protocol Progress:
- ❶ **INITIAL SETUP**
- ❷ **BACKGROUND, RATIONALE & GOALS**
- ❸ **RESEARCH PLAN**
- ❹ **CONSENT PLAN**
- ❺ **RISKS, PRIVACY & CONFIDENTIALITY**
- ❻ **POPULATIONS WITH SPECIAL CONSIDERATIONS**
- ❼ **INSTITUTIONAL REQUIREMENTS**
- ⑧ DOCUMENTS

Click Continue below to go to the next section

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 Form	HM20012696 Informed Consent_02.07.2020_CLEAN.pdf	0.38	4/6/2020 7:08 AM	Caroline Amey	Consent/Assent/Information Sheet	Yes
View	CSTP Vaper Advertisements PDF	WATT_CSTP_Vaper_Combined_02.07.2020_CLEAN.pdf	0.08	2/7/2020 3:43 PM	Rebecca Lester Scholtes	Recruitment/Advertising	Yes
View	CSTP Dual Advertisements PDF	WATT_CSTP_Dual_combined_02.07.2020_CLEAN.pdf	0.03	2/7/2020 3:40 PM	Rebecca Lester Scholtes	Recruitment/Advertising	Yes
View	Baseline Self Report Physio Measures	U54_Baseline forms All_12.18.2019_CLEAN.docx	0.19	12/19/2019 2:23 PM	Caroline Amey	Research Measure	Yes
View	Presession Symptom Questions	WATT Presession symptom Checklist-12.18.2019_CLEAN.docx	0.03	12/19/2019 2:22 PM	Rebecca Lester Scholtes	Research Measure	Yes
View	Text, Email, Call Scripts	U54_Text, Email, Call, Scripts_11.18.2019_CLEAN.docx	0.11	11/25/2019 3:14 PM	Rebecca Lester Scholtes	Other	Yes
View	Own Brand Questions	OB Session Device_E-liquid Questions.9.26.2019_CLEAN.docx	0.03	9/27/2019 10:40 AM	Rebecca Lester Scholtes	Research Measure	Yes
View	BHRL Vaper Advertisements PDF	These advertisements are no longer used by the study.docx	0.08	5/24/2019 12:53 PM	Rebecca Lester Scholtes	Recruitment/Advertising	No
View	BHRL Dual Advertisements PDF	These advertisements are no longer used by the study.docx	0.08	5/24/2019 12:53 PM	Rebecca Lester Scholtes	Recruitment/Advertising	No
View	Parking Map	CSTP Parking Map .docx	0.01	4/30/2019 1:40 PM	Rebecca Lester Scholtes	Other	Yes
View	Session Drug Purchase Task (PRT)	Drug Purchase Tasks_2.19.2019_CLEAN.docx	0.08	3/29/2019 1:16 PM	Caroline Amey	Research Measure	Yes
View	Session Multiple Choice Task (MCP)	Multiple Choice Procedure_1.9.2018_CLEAN.docx	0.04	1/25/2019 2:14 PM	Caroline Amey	Research Measure	Yes
View	Baseline Discounting Task	Discounting Task_11.7.2018.pdf	0.01	11/13/2018 11:37 AM	Caroline Amey	Research Measure	Yes
View		BART_screenshot.11.8.2018.pdf	0.01			Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Baseline Risk taking task - BART			11/13/2018 11:37 AM	Caroline Amey		
View	Session subjective measures	Session Subjective Measures 11.9.2018_CLEAN.docx	0.05	11/13/2018 11:30 AM	Caroline Amey	Research Measure	Yes
View	Session Progressive Ratio Task (PRT)	PRT_Version2_10.12.2018.pdf	0.02	10/16/2018 11:31 AM	Rebecca Lester Scholtes	Research Measure	Yes
View	U54 Project 3 Grant Docs	U54_Project 3 only docs.pdf	0.01	4/4/2018 4:21 PM	Caroline Amey	Funding Proposal	Yes
View	BHRL Registry Consent Form	HM20007677 Consent Form_CLEAN_06.22.2017.pdf	0.01	3/6/2018 11:20 AM	Caroline Amey	Consent/Assent/Information Sheet	Not Applicable
View	Criticare HR/BP Manual	Criticare_Vitalcare_506N3_-_Service_manual.pdf	0.01	3/6/2018 11:20 AM	Caroline Amey	Other	Not Applicable
View	Expired Air CO Manual	CO Monitor Manual.pdf	0.01	3/6/2018 11:19 AM	Caroline Amey	Other	Not Applicable
View	Lipato Biosketch	Lipato Biosketch_10.5.16.docx	0.01	3/6/2018 11:10 AM	Caroline Amey	CV/Biosketch	Yes
View	Barnes Biosketch	P3 Barnes biosketch 06.22.17.FINAL.docx	0.01	3/6/2018 11:09 AM	Caroline Amey	CV/Biosketch	Not Applicable
View	Cobb (Amey) CV	C_Cobb_CV_1.4.2018-2.docx	0.01	3/6/2018 11:08 AM	Caroline Amey	CV/Biosketch	Yes

ID: HM20012696 View: SF2 - Documents Complete

Documents Complete

Protocol Progress:
1. **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**

End of Application

Click Continue below to exit and submit this project

ID: HM20012696 View: Bio-Medical Project Drugs

Bio-Medical Project Drugs

1. * **Drug:**
   Nicotine-containing electronic cigarette liquid (10 and 30 mg nicotine) in tobacco, menthol, dessert, and fruit flavors
2. * **Manufacturer:**
   AVAIL Inc
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
- [x] **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
- [x] **Not Required**

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

ID: HM20012696 View: Bio-Medical Project Drugs

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)***

- ○ 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":**

ID: HM20012696 View: Bio-Medical Project Drugs

Bio-Medical Project Drugs

1. * **Drug:**
   Own brand electronic cigarette liquid
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
- ☑ **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":**

ID: HM20012696 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   In-person consent
2. * **Select all that apply to this consent / assent group:**

Name	
☑	**Written/Signed Consent by Participant**
☐	Written/Signed Consent by Parent/Guardian (for child) or Legally Authorized Representative (for adult)
☐	Written/Signed Consent for Genetic Testing
☐	Written/signed assent by Child or Decisionally Impaired Adult
☐	Verbal Assent by Child
☐	Short Form Consent (limited applicability)
☐	None of the Above (select waiver below)

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

☑	**No Waivers Requested**
☐	Waiver of Some or All Elements of Consent
☐	Waiver of Assent by Child or Decisionally Impaired Adult
☐	Waiver of Parental Permission or Legally Authorized Representative Consent
☐	Waiver of Documentation of Consent/Assent (not signed)
☐	Exception from Informed Consent (for emergency research only)

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

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

- [x] **Research Coordinator**
- [ ] Research Nurse
- [ ] Consultant
- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [x] **Trainee/Student (i.e. not Student-Investigator)**
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

5. * **Describe the consent procedures used for this group. Include when, where, and how consent / assent will be obtained both initially and, if applicable, during ongoing participation in the study:**
   In a private room located at the Center for the Study of Tobacco Products (CSTP) or Behavioral Health Research Lab (BHRL).
6. * **Describe the process for minimizing coercion to participate:**
   Participants are read the consent form aloud and encouraged to ask questions before signing.
7. * **How much time will participants be given to make a decision:**
   As much time as necessary.
8. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**

ID: HM20012696 View: Personnel

Personnel

1. * **Name:**
   Caroline 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
- [ ] Student Investigator
- [ ] 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.

   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
   - [ ] Student Investigator
   - [ ] 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:**

ID: HM20012696 View: Personnel

Personnel

1. * **Name:**
   Rebecca Lester Scholtes
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
- [ ] Student Investigator
- [x] **Research Coordinator**
- [x] **Research Assistant**
- [ ] 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:**
   Cosima Hoetger
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
   - ☐ Student Investigator
   - ☑ **Research Assistant**
   - ☑ **Trainee/Student (i.e. not Student-Investigator)**
   - ☐ Other
4. * **Study related responsibilities:**

   - ☐ Study Design
   - ☑ **Data Collection - Lab**
   - ☐ Data Collection - Clinical
   - ☑ **Data Collection - Interviews/Surveys**
   - ☑ **Data Collection - Direct Observation**
   - ☐ Clinical Services
   - ☐ Intervention Services
   - ☑ **Data Entry**
   - ☑ **Data Coding**
   - ☑ **Data Management**
   - ☑ **Data Analysis**
   - ☑ **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
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**

ID: HM20012696 View: Personnel

Personnel

1. * **Name:**
   Alyssa Rudy
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

Student Investigator

- [ ]
- [x] **Research Assistant**
- [x] **Trainee/Student (i.e. not Student-Investigator)**
- [ ] 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**
- [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

- [ ]
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**

ID: HM20012696 View: Personnel

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.

   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
   - [ ] Student Investigator
   - [ ] 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

     Data Management

- [ ]
- [x] **Data Analysis**
- [x] **Project Coordination**
- [ ] 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
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

ID: HM20012696 View: Personnel

Personnel

1. * **Name:**
   Rose Bono
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
- [ ] Student Investigator
- [x] **Research Assistant**
- [x] **Trainee/Student (i.e. not Student-Investigator)**
- [ ] Other

4. * **Study related responsibilities:**

- [ ] Study Design
- [ ] Data Collection - Lab
- [ ] Data Collection - Clinical
- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [x] **Data Entry**
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [ ] Project Coordination
- [ ] Participant Identification
- [x] **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**
- [ ] **Experience - Research**

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

7. **Additional or Emergency Phone:**

ID: HM20012696 View: Personnel

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
   - [ ] Co/Sub-Investigator
   - [ ] Medical or Psychological Responsible Investigator
   - [ ] Student Investigator
   - [x] **Other**
4. * **If other role is selected, explain:**
   Dr. Breland is the PI for a similar study. We will exclude participants who have participated in Dr. Breland's study and she will exclude participants who have participated in this study. Thus, Dr. Breland is on this protocol so that we can cross-check participants to ensure that a participant does not complete both similar studies.
5. * **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**
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [x] **Project Coordination**
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

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:**
   Individual has no clinical responsibilities
7. * **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

8. **Additional or Emergency Phone:**

ID: HM20012696 View: Personnel

Personnel

1. * **Name:**
   Barbara Kilgalen
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
- ☐ Student Investigator
- ☑ **Research Nurse**
- ☐ Other

4. * **Study related responsibilities:**

- ☐ Study Design
- ☑ **Data Collection - Lab**
- ☐ Data Collection - Clinical
- ☑ **Data Collection - Interviews/Surveys**
- ☑ **Data Collection - Direct Observation**
- ☑ **Clinical Services**
- ☐ Intervention Services
- ☑ **Data Entry**
- ☑ **Data Coding**
- ☑ **Data Management**
- ☑ **Data Analysis**
- ☐ Project Coordination
- ☑ **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:**

ID: HM20012696 View: Personnel

Personnel

1. * **Name:**
   Melanie Crabtree
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
- [ ] Student Investigator
- [x] **Research Assistant**
- [ ] 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**
- [ ] 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:**

ID: HM20012696 View: Personnel

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**
- [ ] Student Investigator
- [ ] Other

4. * **Study related responsibilities:**

- [ ] Study Design
- [x] **Data Collection - Lab**
- [ ] Data Collection - Clinical
- [x] **Data Collection - Interviews/Surveys**
- [ ] Data Collection - Direct Observation
- [x] **Clinical Services**
- [ ] Intervention Services
- [x] **Data Entry**
- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis
- [ ] Project Coordination
- [ ] 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**
- [ ] Experience - Clinical
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

ID: HM20012696 View: Personnel

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.

   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
   - [ ] Student Investigator
   - [x] **Research Assistant**
   - [x] **Trainee/Student (i.e. not Student-Investigator)**
   - [ ] Other

4. * **Study related responsibilities:**

   - [x] **Study Design**
   - [x] **Data Collection - Lab**
   - [ ] Data Collection - Clinical

   Data Collection - Interviews/Surveys

- [x]
- [x] **Data Collection - Direct Observation**
- [ ] Clinical Services
- [ ] Intervention Services
- [x] **Data Entry**
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [ ] 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
- [x] **Trainee**
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**

ID: HM20012696 View: Personnel

Personnel

1. * **Name:**
   Megan Underwood

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
- ☐ Student Investigator
- ☑ **Research Assistant**
- ☐ Other

4. * **Study related responsibilities:**

- ☐ Study Design
- ☑ **Data Collection - Lab**
- ☐ Data Collection - Clinical
- ☑ **Data Collection - Interviews/Surveys**
- ☑ **Data Collection - Direct Observation**
- ☐ Clinical Services
- ☐ Intervention Services
- ☑ **Data Entry**
- ☑ **Data Coding**
- ☑ **Data Management**
- ☑ **Data Analysis**
- ☐ Project Coordination
- ☑ **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)**

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

7. **Additional or Emergency Phone:**

ID: HM20012696 View: Personnel

Personnel

1. * **Name:**
   Alisha Eversole

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
- [ ] Student Investigator
- [x] **Research Assistant**
- [x] **Trainee/Student (i.e. not Student-Investigator)**
- [ ] 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**
- [ ] 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
- [x] **Experience - Related Skills**
- [ ] Trainee
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Sarah Maloney
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
   - ☐ Student Investigator
   - ☑ **Research Assistant**
   - ☐ Other
4. * **Study related responsibilities:**

   - ☐ Study Design
   - ☑ **Data Collection - Lab**
   - ☐ Data Collection - Clinical
   - ☑ **Data Collection - Interviews/Surveys**
   - ☑ **Data Collection - Direct Observation**
   - ☐ Clinical Services
   - ☐ Intervention Services
   - ☑ **Data Entry**
   - ☑ **Data Coding**
   - ☑ **Data Management**
   - ☑ **Data Analysis**
   - ☐ Project Coordination
   - ☑ **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
- [x] **Experience - Related Skills**
- [ ] Trainee
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**

ID: HM20012696 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Informed Consent Form
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   HM20012696 Informed Consent_02.07.2020_CLEAN.pdf(0.38)

ID: HM20012696 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   CSTP Vaper Advertisements PDF
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   WATT_CSTP_Vaper_Combined_02.07.2020_CLEAN.pdf(0.08)

ID: HM20012696 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   CSTP Dual Advertisements PDF
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   WATT_CSTP_Dual_combined_02.07.2020_CLEAN.pdf(0.03)

ID: HM20012696 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Baseline Self Report Physio Measures
2. * **Type:**
   Research Measure
3. * **File:**
   U54_Baseline forms All_12.18.2019_CLEAN.docx(0.19)

ID: HM20012696 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Presession Symptom Questions
2. * **Type:**
   Research Measure
3. * **File:**
   WATT Presession symptom Checklist-12.18.2019_CLEAN.docx(0.03)

ID: HM20012696 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Text, Email, Call Scripts
2. * **Type:**
   Other
3. * **File:**
   U54_Text, Email, Call, Scripts_11.18.2019_CLEAN.docx(0.11)

ID: HM20012696 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Own Brand Questions
2. * **Type:**
   Research Measure
3. * **File:**
   OB Session Device_E-liquid Questions.9.26.2019_CLEAN.docx(0.03)

ID: HM20012696 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   BHRL Vaper Advertisements PDF
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   These advertisements are no longer used by the study.docx(0.08)

ID: HM20012696 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   BHRL Dual Advertisements PDF
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   These advertisements are no longer used by the study.docx(0.08)

ID: HM20012696 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Parking Map
2. * **Type:**
   Other
3. * **File:**
   CSTP Parking Map .docx(0.01)

ID: HM20012696 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Session Drug Purchase Task (PRT)
2. * **Type:**
   Research Measure
3. * **File:**
   Drug Purchase Tasks_2.19.2019_CLEAN.docx(0.08)

ID: HM20012696 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Session Multiple Choice Task (MCP)
2. * **Type:**
   Research Measure
3. * **File:**
   Multiple Choice Procedure_1.9.2018_CLEAN.docx(0.04)

ID: HM20012696 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Baseline Discounting Task
2. * **Type:**
   Research Measure
3. * **File:**
   Discounting Task_11.7.2018.pdf(0.01)

ID: HM20012696 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Baseline Risk taking task - BART
2. * **Type:**
   Research Measure

3. * **File:**
   BART_screenshot.11.8.2018.pdf(0.01)

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1. * **Document Name:**
   Session subjective measures
2. * **Type:**
   Research Measure
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   Session Subjective Measures 11.9.2018_CLEAN.docx(0.05)

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1. * **Document Name:**
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2. * **Type:**
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   PRT_Version2_10.12.2018.pdf(0.02)

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1. * **Document Name:**
   U54 Project 3 Grant Docs
2. * **Type:**
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   BHRL Registry Consent Form
2. * **Type:**
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   HM20007677 Consent Form_CLEAN_06.22.2017.pdf(0.01)

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   Criticare HR/BP Manual
2. * **Type:**
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   Criticare_Vitalcare_506N3_-_Service_manual.pdf(0.01)

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2. * **Type:**
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1. * **Document Name:**
   Barnes Biosketch
2. * **Type:**
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   P3 Barnes biosketch 06.22.17.FINAL.docx(0.01)

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1. * **Document Name:**
   Cobb (Amey) CV
2. * **Type:**
   CV/Biosketch
3. * **File:**
   C_Cobb_CV_1.4.2018-2.docx(0.01)