Cover sheet for protocol HM20018290/NCT04332926

The stats section is from the grant. Our institution now requires a protocol when submitting to the IRB, it was not required when this study was approved. The final version of the study was approved by the IRB 3/21/2024 and the last consent form approved was 2/27/23.

predicted to be the lowest in the 4 mg/ml/8W condition for both exclusive and dual users and highest in the 24 mg/ml/8W condition (exclusive ECIG users' willingness to work 600 vs. 1100 bar presses; dual ECIG+TCig users 375 vs. 690 bar presses). Results revealed that for within-and between-subjects analyses for the $breakpoint_{MCP}$ and $breakpoint_{PRT}$, 60 participants were required to achieve power $\geq$80% given α<0.05. We excluded own brand controls to ensure we are powered to detect differences across experimental conditions.

Aim 1 Procedure. Study 1's method is modeled on our work (e.g., Barnes et al., 2017; Vansickel et al., 2012) and that of others (e.g., Audrain-McGovern et al., 2016; Rusted et al., 1998). Exclusive ECIG users (N=60) and dual ECIG+TCig users (N=60) will attend the lab for 5 sessions, corresponding to a 2 (power: low, high W) by 2 (nicotine concentration: low, high mg/ml) design with own brand ECIG/cigarette control (see Fig 2 above). In all experimental ECIG conditions, participants will use a variable-voltage ECIG (Kanger Cupti with a 0.5-ohm heating element; chosen based on predicted nicotine yield, Talih et al., 2017) loaded with the condition-specific nicotine concentration (e.g., 4 or 24 mg/ml). Power is manipulated by altering voltage to 2 or 4.5 V ($W=V^2/R$, yielding 8 or 40 W). For the own brand ECIG condition, participants will bring their preferred device for use. We will purchase their own brand ECIG liquid/disposable products and own brand tobacco cigarettes (reported during screening). Each session will be preceded by 12 hours tobacco/nicotine abstinence (to increase the likelihood of product use during the session and control for differing patterns of use); expired air CO $\leq$10 ppm is required. The session commences with sampling of the session-specific product (2 puffs) followed by 1 hour rest. These procedures ensure initial experience with the session product (as in Copp et al., 2015; Audrain-McGovern et al., 2016) and controls for time of last tobacco/nicotine use (as in Bickel & Madden, 1999). After the rest period, baseline subjective measures to assess tobacco abstinence symptoms will be completed and then either the PRT or DPT/MCP tasks will be completed with a 60-minute rest period in between each set of tasks. 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. The rest period between task sets reduces the influence of nicotine exposure/reinforcements received (specifically during the PRT and MCP). Each task set is preceded and followed by tobacco abstinence symptom assessment for a total of 4 assessments within each session (before and after task set 1, before and after task set 2). The PRT takes about 30 minutes to complete. The DPT takes between 5-10 minutes. After the DPT measures, the MCP will be administered immediately, which will take ~30 minutes. Each session is estimated to take ~3.25 hours.

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.

Aim 2 design, method, sample size and power, and procedure. This aim involves a lab-based study (Study 2) that manipulates nicotine flux systematically, testing the hypothesis that abstinence suppression and nicotine delivery will be related directly to flux, independent of tobacco cigarette use. No previous study has manipulated nicotine flux and examined between-group effects, so we could not estimate effect size. Thus, we adopted the same sample sizes as in Study 1 (N=60/group), and note that this sample size exceeds that required to achieve power >0.80 with α<0.05 and assuming a small effect size (Cohen's **f**=0.20) and moderate repeated measures correlation (r=0.5) in a mixed ANOVA with device power and puff duration as within-subjects factors (i.e., 58/group; GPower). In Study 2, 60 exclusive ECIG users and 60 ECIG+TCig users will attend the lab for 5 sessions, corresponding to a 2 (device power: low, high W) by 2 (puff duration: short, long) design with own brand ECIG/cigarette control (always session 5; see Fig 2). In all experimental ECIG conditions, participants will use the same ECIG as in Study 1, with nicotine concentration that is based on Project 2's Aim 1 results (e.g., 8 mg/ml). Puff duration will be controlled electronically using hardware developed by Project 1 (i.e., the device will power off after the desired puff duration). Products for own brand conditions will be obtained and used without power or duration restrictions as in Aim 1. Session procedures are as described for Study 1. We hypothesize that flux will be related directly to willingness to pay/work (DPT, MCP, PRT) and inversely to price sensitivity (DPT) for all users. This study informs regulation by examining, in exclusive ECIG users and dual ECIG+TCig users, the effects of constraining nicotine flux.

Aim 3 design, method, sample size and power, and procedure. This aim involves a lab-based study (Study 3) in which ECIG flavor is manipulated across four levels (e.g., preferred, dessert, fruit, none) while nicotine flux is held constant. ECIG liquids have 1000s of flavors (Zhu et al., 2014), ECIG users have flavor preferences (e.g.,

Bonhomme et al., 2016; Wang et al., 2015), and ECIG flavor is associated with increased rewarding properties (Audrain-McGovern et al., 2016), reduced perceived harshness (Kim et al., 2016), and smoking cessation (e.g., Camenga et al., 2016). For Aim 3 sample size and power, we use estimates from Barnes et al. (2017) and a repeated measures design predicting outcomes used in Aim 1. For our analyses, we predict the $breakpoint_{MCP}$ in the preferred ECIG flavor condition to be more than twice that for the no flavor condition for dual ECIG+TCig users ($1.30 vs. $0.52), but exclusive ECIG users will have a breakpoint for the preferred ECIG flavor condition that is more than twice that for dual users ($3.05). Similarly, elasticity is predicted to be the lowest for the preferred ECIG flavor condition for exclusive ECIG users (elasticity=0.02) and dual users (elasticity=0.05), while elasticity will be highest for no flavor ECIGs (~0.10; supported by Barnes et al., 2017). Data from Audrain-McGovern et al. (2016) indicate exclusive ECIG and dual ECIG+TCig users will work 4x harder for their preferred flavor vs. no flavor ECIGs (600 vs. 130 presses), with exclusive ECIG users willing to work more for reinforcers in each condition. For $breakpoint_{MCP}$, $breakpoint_{PRT}$ and elasticity, using estimates for differences between ECIG liquid flavor condition, within-subjects and between-subjects analyses require 60 participants to achieve power $\geq$80% given α<0.05. In Study 3, 60 exclusive ECIG and 60 dual ECIG+TCig users will attend the lab for 5 sessions. In the first four randomly ordered sessions, they will use an ECIG set at a power setting and liquid with a nicotine concentration informed by the results of Project 2's Study 1 varying only in flavor (preferred flavor, dessert flavor, fruit flavor, and unflavored liquid). Session 5 for all participants will be either an own brand ECIG or own brand tobacco cigarette (ECIG+TCig only) control (see Fig 2). Products for own brand ECIG and tobacco cigarette conditions and session procedures will be as in Study 1. We hypothesize that abuse liability indices will vary by flavor more for exclusive vs. dual users (preferred > dessert/fruit > none). This pattern highlights how ECIG abuse liability is affected by flavor availability.

Summary and potential concerns. This project has three aims and proposes three well-powered studies to address them. All of the studies inform tobacco regulatory science by examining hypotheses regarding advanced-generation ECIGS. They are an integral part of a transdisciplinary center focused on developing tools that can predict tobacco product regulatory impact. Below we address some potential concerns.

Can you find enough exclusive ECIG users and dual ECIG+TCig users? Yes. We have completed several studies of experienced ECIG users (e.g., Spindle et al., 2015, 2017; Hiler et al., in press, Vansickel et al., 2012). Examination of our CSTP-wide online screening data (N=2,043) indicates dual ECIG+TCig users can be found with 14% (N=293) reporting daily tobacco cigarette smoking and daily ECIG liquid use. With ECIG use increasing annually, we anticipate little difficulty recruiting the needed participants over a 5-year period.

Will there be carryover across assessments within a session? We counterbalance the PRT and the MCP/DPT task sets across participants to control for the effects of completing one task set prior to the other. The rest period between task sets reduces the influence of nicotine exposure/reinforcements received.

Why focus on these three regulations? Nicotine liquid limits have been enacted by the EU, flux constraints have empirical support (Talih et al., 2017), and reduced flavor availability is a likely outcome after November 2019 when FDA authorization is required to market ECIG liquids. However, many potential regulations addressing product manufacturers can be examined using Project 3 methods. We chose these three as examples. Our methods are flexible and can be applied to a variety of products and potential regulations.

Why include dual users and not exclusive smokers? Feasibility and cost forced us to choose. Dual use is much discussed (e.g., Breland et al., 2017), and many Project 3 outcomes are relevant particularly to dual users who either may transition to exclusive ECIG use or to exclusive smoking. Project 2 includes exclusive smokers.

Have we adequately described our methods? Our P50 application was criticized for not including enough detail. Space constraints limit the detail provided here. We invite reviewers to refer to our publications, in which very similar methods are described (e.g., Barnes et al., 2017, Vansickel et al., 2012, Bickel & Madden, 1999).

Can the work be completed in five years? Yes. Studies 1, 2, and 3 each involve 600 sessions (exclusive: 5x60; dual: 5X60), for a total of 1,800 sessions. Assuming 20% attrition (some participants will complete at least one session but then fail to complete others and need to be replaced), we estimate that we will need to complete 2,160 sessions over 5 years. Since the BHRL initiated formal recruitment in January 2015 (~2.5 years) four unique lab studies among cigarette and ECIG using populations (including dual users) have been completed requiring >750 sessions. With additional lab space/staffing proposed here, in 5 years we can complete 2,160 sessions. We will begin Study 1 early in Year 1 completing it at end of Year 2. Study 2 will begin soon thereafter. We will complete it in the middle of Year 4, and Study 3 will be completed near the end of Year 5.

Study Identification

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

2. * **Study Title:**
   Effects of E-Cigarette Nicotine Delivery on Abuse Liability in Smokers (Project 3 Flux Study)

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

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

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

ID	Title	PI
HM20002567	CSTP Overall Screening and Registry	Caroline Cobb Amey
HM20007677	Behavioral Health Research Laboratory Screening and Registry	Caroline Cobb Amey
HM20018580	Assessing Electronic Cigarette Nicotine Flux (Project 2 Flux Study)	Alison Breland

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

Last Name	First Name	E-Mail	Phone	Mobile
Amey	Caroline Cobb	cobbco@vcu.edu		
Barnes	Andrew	abarnes3@vcu.edu		
Breland	Alison	abbrelan@vcu.edu		
Gaitan	Nicoleta	gaitann@vcu.edu		
Imran	Rabia	imranr@vcu.edu		

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

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

Federal Regulations

1. * Is this a FDA regulated study?

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

- (●) **Yes**
- ( ) No

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

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

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

- ( ) Yes
- (●) **No**

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

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

HM20018290 - Caroline Cobb Amey
Effects of E-Cigarette Nicotine Delivery on Abuse Liability in Smokers (Project 3 Flux Study)

IRB Panel Setup

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

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

HM20018290 - Caroline Cobb Amey
Effects of E-Cigarette Nicotine Delivery on Abuse Liability in Smokers (Project 3 Flux Study)

Review Setup

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

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

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

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

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

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

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

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

HM20018290 - Caroline Cobb Amey
Effects of E-Cigarette Nicotine Delivery on Abuse Liability in Smokers (Project 3 Flux Study)

Initial Setup Complete

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

Click Continue below to go to the next section

Background, Rationale and Goals

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

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

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

   To do so, we use behavioral economic indices of abuse liability to examine to hypotheses related to three potential regulatory actions: limiting nicotine concentration (ongoing study in HM20012696), constraining nicotine flux (nicotine yield/unit time; described here), and reducing flavor availability (these will be tested in other studies). We then use results from clinical lab studies described here, along with results from other studies, to generate predictions about how these potential regulatory actions might impact the population, and then test our predictions at the population level (in a separate study not described in this protocol).

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

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

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

2. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
   The purpose of this study is to determine if abuse liability indices will be impacted by differences in electronic cigarette (ECIG) nicotine flux among current combustible cigarette users. Nicotine flux will be controlled by using an electronic cigarette with constant device settings (30 Watts; 2 second puff duration) and different e-liquid concentrations (0 mg/ml, 6 mg/ml, 15 mg/ml, and 30 mg/ml). We will compare abuse liability indices between ECIG conditions as well as for own brand cigarette smoking.

   We hypothesize that as nicotine flux is lowered, abuse liability indices will be lowered, as assessed by less willingness to pay/work for ECIG puffs and more price sensitivity.

   We also hypothesize smokers will substitute from own brand cigarettes to ECIGs more quickly for ECIGs with nicotine flux conditions that most closely approximate the flux produced by cigarette smoking.

3. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
   The aim of this study is to better understand how ECIG nicotine flux impacts several behavioral economic measures of abuse liability.

   Results will be used to inform future tobacco product regulations of these ECIG liquid and 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 the appropriate regulation of ECIGs.

   In particular, the use of ECIGs has become increasingly popular, especially among individuals aged 18-24. New regulations are being targeted at this age group and need to be tested in this age group before implementation. The overarching theme of the Center for the Study of Tobacco Products is to provide regulators (FDA and others) with a suite of tools that allow them to test regulations before they are implemented to determine if those regulations will have their intended consequences without causing harm (i.e., unintended consequences). If we cannot study the age group the regulations are targeting, we cannot test potential regulations effectively.

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

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

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

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

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Informed Consent	P3 FLUX_Informed Consent_12.07.2022_CLEAN.pdf	0.29	2/27/2023 12:23 AM	Rebecca Scholtes	Consent/Assent/Information Sheet	Yes
View	Consent - Tool	P3FLUX_Consent_Presentation_12.07.2022_CLEAN.pptx	0.13	12/7/2022 2:37 PM	Rebecca Scholtes	Other	Yes
View	Text, Email, Call Scripts	Phone_e-mail_text scripts_CLEAN__12.07.2022.docx	0.19	12/7/2022 2:35 PM	Rebecca Scholtes	Other	Yes
View	COVID-19 Questions	NO LONGER USING_COVID_Questions_P3_12.07.2022.docx	0.06	12/7/2022 2:33 PM	Rebecca Scholtes	Other	No
View	Information about Blood Pressure	BP results P3 flux 8.22.2022.docx	0.01	8/22/2022 11:43 AM	Rabia Imran	Other	Yes
View	P3 Flux Advertisement for CSTP Website	P3 FLUX Description for CSTP Website_CLEAN_03.30.2022.docx	0.05	4/13/2022 10:36 AM	Rebecca Scholtes	Recruitment/Advertising	Yes
View	Referral Program Card Template	P3_Referral program card_1.13.2022.docx	0.01	1/14/2022 11:49 AM	Caroline Cobb Amey	Recruitment/Advertising	Yes
View	Baseline Self Report Physio Measures	P3- FLUX_Baseline forms All_5.21.2021_CLEAN.docx	0.14	5/24/2021 2:01 PM	Rebecca Scholtes	Research Measure	Yes
View	Follow-up Survey	P3-FLUX-Follow-up_05.21.2021_CLEAN.docx	0.11	5/24/2021 1:59 PM	Rebecca Scholtes	Research Measure	Yes
View	CP-DPT & DPT - Tool	DPT_CDPT presentation_04.26.2021_CC.pptx	0.03	4/26/2021 4:36 PM	Rebecca Scholtes	Other	Yes
View	DPT/CP-DPT - Tool VIDEO	DPT_CDPT presentation_04.26.2021_CC.mp4	0.02	4/26/2021 4:35 PM	Rebecca Scholtes	Other	Yes
View	Drug Purchase Tasks (DPT)	P3-FLUX-Drug Purchase Tasks_04.26.2021_CLEAN.docx	0.03	4/26/2021 12:23 PM	Rebecca Scholtes	Research Measure	Yes
View	Puff Limiting Software Details	P3-Flux Puff Limiting Software.docx	0.01	3/19/2021 3:54 PM	Caroline Cobb Amey	Other	Not Applicable
View	Consent - Tool VIDEO	No_Longer_Using_This_Tool.docx	0.03	1/26/2021 11:37 AM	Rebecca Scholtes	Other	No
View	Facebook Advertisements	facebook ads_01.25.2021.docx	0.01	1/26/2021 10:16 AM	Rebecca Scholtes	Recruitment/Advertising	Yes
View	Combined PRT/CP-PRT - Tool	1.19_21_combinedPRT_instructions..pptx	0.02	1/25/2021 9:20 PM	Rebecca Scholtes	Other	Yes
View	Progressive Ratio Task (PRT)	PRT_FLUX_V3_1.22.21.pdf	0.03	1/25/2021 9:19 PM	Rebecca Scholtes	Research Measure	Yes
View	Subjective Measures	P3-FLUX-Session Subjective Measures_01.25.2021_CLEAN.doc	0.05	1/25/2021 4:45 PM	Rebecca Scholtes	Research Measure	Yes
View	CP-PRT - Tool	No_Longer_Using_This_Tool.docx	0.02	9/30/2020 1:48 PM	Rebecca Scholtes	Other	No
View	PRT - Tool	No_Longer_Using_This_Tool.docx	0.02	9/30/2020 1:47 PM	Rebecca Scholtes	Other	No

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Subjective Measures - Tool VIDEO	Subjective Measures presentation_09.02.2020.mp4	0.01	9/9/2020 10:54 PM	Rebecca Scholtes	Other	Yes
View	Subjective Measures -Tool	Subjective Measures presentation_09.02.2020.pptx	0.02	9/9/2020 10:38 PM	Rebecca Scholtes	Other	Yes
View	Cross Product Progressive Ratio Task (CP-PRT)	CP_PRT_Flux_V2_08.04.2020.pdf	0.02	8/17/2020 11:46 AM	Rebecca Scholtes	Research Measure	Yes
View	Flux Advertisements	FLUX_Combined Ads_07.20.2020_V3_CLEAN.pdf	0.05	7/20/2020 10:32 AM	Rebecca Scholtes	Recruitment/Advertising	Yes
View	CSTP Registry Consent Document	CSTP_Consent and screening_registry questions updated 4.29.19 CHANGES ACCEPTED.pdf	0.01	4/2/2020 3:36 PM	Rebecca Scholtes	Consent/Assent/Information Sheet	Not Applicable
View	BHRL Registry Consent Document	HM20007677 Consent Form_06.21.2019_CLEAN.pdf	0.01	4/2/2020 3:33 PM	Rebecca Scholtes	Consent/Assent/Information Sheet	Not Applicable
View	Presession Symptom Questions	P3-FLUX-Presession symptom Checklist-01.09.2019.docx	0.01	4/2/2020 12:47 AM	Rebecca Scholtes	Research Measure	Yes
View	Barnes Biosketch	P3 Barnes biosketch 06.22.17.FINAL.docx	0.01	4/1/2020 11:23 PM	Rebecca Scholtes	CV/Biosketch	Not Applicable
View	Lipato Biosketch	Lipato Biosketch_10.5.16.docx	0.01	4/1/2020 11:22 PM	Rebecca Scholtes	CV/Biosketch	Yes
View	Caroline Cobb (Amey) CV	Curriculum Vitae_Cobb_December 2019.docx	0.01	3/9/2020 11:16 AM	Caroline Cobb Amey	CV/Biosketch	Yes
View	Baseline Discounting Task - MDT	P3_FLUX_Discounting Task_11.7.2018.pdf	0.01	3/6/2020 1:26 PM	Rebecca Scholtes	Research Measure	Yes
View	Baseline Risk Taking Task - BART	P3_FLUX_BART_screenshot.11.8.2018.pdf	0.01	3/6/2020 1:26 PM	Rebecca Scholtes	Research Measure	Yes
View	U54 Project 3 Grant Docs	U54_Project 3 only docs.pdf	0.01	3/6/2020 12:51 PM	Rebecca Scholtes	Funding Proposal	Not Applicable
View	CSTP Parking Map	CSTP Parking Map .docx	0.01	3/6/2020 12:28 PM	Rebecca Scholtes	Other	Yes
View	Criticare HR/BP Manual	Criticare_Vitalcare_506N3_-_Service_manual.pdf	0.01	3/6/2020 12:28 PM	Rebecca Scholtes	Other	Not Applicable
View	Expired Air CO Manual	CO Monitor Manual.pdf	0.01	3/6/2020 12:27 PM	Rebecca Scholtes	Other	Not Applicable

Study Population

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

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

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

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

3. * **Provide justification for the sample size by explaining how you arrived at the expected number of participants and why this number is adequate for answering the research questions:**
   This study manipulates e-cigarette nicotine flux systematically, testing the hypothesis that abuse liability will be related directly to flux among a sample of cigarette smokers. No previous study has manipulated nicotine flux and examined within-group effects, so we could not estimate effect size. Thus, we calculated a sample size to achieve a power of >0.80 with α <0.05 and assuming a small effect size (Cohen's f=0.20) and moderate repeated measures correlation (r=0.5) in a repeated measures ANOVA with nicotine flux as within-subjects factors (N=32; GPower). In Study 2, 40 cigarette users will attend the lab for 5 sessions - no flux, low flux, cigarette-like flux, high flux, and an own brand cigarette control (always session 5). We hypothesize that flux will be positively associated with willingness to pay/work (drug purchase task, progressive ratio task) and willingness to substitute e-cigarettes for own brand cigarettes (cross-product drug purchase task, cross-product progressive ratio task), and inversely to price sensitivity (drug purchase task) for all smokers.

   It is possible that we would consent up to 100 participants in order to obtain 40 participants who complete the entire study.

4. * **List the study inclusion criteria:**
   All participants must be healthy (determined by self-report), between the ages of 18-55 (verified by photo ID), willing to provide informed consent, and attend the lab and abstain from tobacco/nicotine as required. Participants must agree to use designated products according to the study protocol.

   Participants must use at least 5 cigarettes per day if they are not classified as dual users of inhaled tobacco products.

   Participants classified as dual users of inhaled tobacco products must meet at least of two definitions described below:

   -at least some day use of cigarettes (≥3 days per week at any cigarettes per day frequency) AND
   -daily use of another inhaled tobacco product (e.g., e-cigarettes, cigars, pipe)

   OR

   -daily use of cigarettes (at any cigarettes per day frequency) AND
   -at least some day use of another inhaled tobacco product (e.g., e-cigarettes, cigars, pipe; ≥3 days per week at any frequency).

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

   Please note that beginning July 1, 2020, per HB1570, we will recruit individuals aged 18-55. This law "Provides an exception to the law prohibiting possession of tobacco products, nicotine vapor products, or alternative nicotine products by a person less than 21 years of age when such possession is part of a scientific study being conducted by an organization for the purpose of medical research to further efforts in cigarette and tobacco use prevention and cessation and tobacco product regulation, provided that such medical research has been approved by an institutional review board pursuant to applicable federal regulations or by a research review committee." We will not enroll any participants under the age of 21 until after July 1, 2020.

5. * **List the study exclusion criteria:**
   Individuals with the following self-reported current, diagnosed medical condition(s) will be excluded automatically: uncontrolled high blood pressure (i.e., self-reported and/or observed at screening; BP above 160/100), 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, and who are currently under the care of a physician for psychiatric conditions, or who report current psychiatric treatment or psychotropic medication use will be excluded.

Individuals with past-month use of other illicit drugs including cocaine, opioids, benzodiazepines, and methamphetamine will be excluded.

Individuals who report using marijuana >=16 days in the past 30 and/or alcohol >= 26 days in the past 30 days will be excluded.

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

Use of other tobacco products (other that cigarettes) at any frequency will NOT be exclusionary.

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

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

In addition, participants who have previously participated in a study with exactly the same manipulations of ECIG type, setting, and liquid concentration will be excluded. Specifically, participants who have participated in HM20018580 will not be eligible to participate in this protocol. Staff from this protocol will work with staff from HM20018580 (who are also listed on this protocol) to assure that there is no cross-participation between participants.

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

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

7. **Justify the inclusion and exclusion criteria if you are either targeting, or excluding, a particular segment of the population / community. Provide a description of the group/organization/community and provide a rationale.**
We are excluding individuals (<18 years old) as this group includes children for whom research risks may differ compared those 18 or older. This younger age group is also likely to differ in important ways compared to individuals aged 18 and older including likelihood of residing with a guardian/parent which may impact their response to research questions of interest. We also exclude pregnant/breastfeeding 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.

HM20018290 - Caroline Cobb Amey
Effects of E-Cigarette Nicotine Delivery on Abuse Liability in Smokers (Project 3 Flux Study)

Background, Rationale & Goals Section Complete

[redacted] Progress:
[redacted]L SETUP
[redacted]KGROUND, RATIONALE & GOALS
③ RESEARCH PLAN
④ CONSENT PLAN
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Study Procedures

1. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
The purpose of this study is to determine if abuse liability indices will be impacted by differences in electronic cigarette (ECIG) nicotine flux among current combustible cigarette users. Nicotine flux will be controlled by using an electronic cigarette with constant device settings (30 Watts; 2 second puff duration) and different e-liquid concentrations (0 mg/ml, 6 mg/ml, 15 mg/ml, and 30 mg/ml). We will compare abuse liability indices between ECIG conditions as well as for own brand cigarette smoking.

We hypothesize that as nicotine flux is lowered, abuse liability indices will be lowered, as assessed by less willingness to pay/work for ECIG puffs and more price sensitivity.

We also hypothesize smokers will substitute from own brand cigarettes to ECIGs more quickly for ECIGs with nicotine flux conditions that most closely approximate the flux produced by cigarette smoking.

2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
The aim of this study is to better understand how ECIG nicotine flux impacts several behavioral economic measures of abuse liability.

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

3. * **Choose all types of recruitment materials that may be used and upload them below:**

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

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

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

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

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

See the help text for additional guidance.
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 websites/apps such as facebook, twitter, instagram, etc. 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 (HM20018290).

Interested individuals will respond to recruitment materials by visiting the screener survey/registry webpage (HM20002567/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. Individuals who consent to the registry and complete screening questions will be evaluated for eligibility by HM20002567/HM20007677 staff, these individuals will always be concurrent staff on the current protocol (HM20018290).

If potentially eligible, HM20002567/HM20007677/HM20018290 staff will use administrative features (i.e., administrative fields/forms) in REDCap to create an internal report that is used to contact/follow-up potentially eligible and enrolled participants for the current protocol using their registry ID. No data will be directly transferred to the current protocol to or from either registry. Use of administrative fields and study staff that are aware of their responsibilities on related protocols eliminates the need for this additional activity.

At the in-person informed consent/screening appointment, participants will first complete informed consent procedures. After agreeing to be in the study, participants are assigned a unique numeric code (study ID) specific to this protocol. This study ID is used to identify all subsequent study-related information/data. Following enrollment, the study ID is added to the participant's registry record/ID (HM20002567/HM20007677) in an administrative form thus electronically linking the registry ID (where contact information is housed) to their study ID (HM20018290). This technique is used so we can communicate effectively with participants as well as reduce the number of places/REDCap projects where participant contact information is stored. The study ID field (HM20018290) is deleted from the registry project (HM20002567/HM20007677) when recruitment for the study has been completed.

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

- ○ Yes
- ● **No**

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

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

See the help text for additional guidance
Overview. This study involves 40 CIG users who will complete 5, within-subject, laboratory conditions that differ by the product used: 1) 30 W; 0 mg/ml; 2 sec puff, 2) 30 W; 6 mg/ml; 2 sec puff, 3) 30 W; 15 mg/ml; 2 sec puff, 4) 30 W; 30 mg/ml; 2 sec puff, and 5) own brand (tobacco cigarette). The first 4 ECIG 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 CIG.

Participants. A total of 40 adults (ages 18-55) who currently use CIGs 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.

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 be invited to the lab to complete in-person informed consent, additional screening, and familiarization with study procedures (approximately 2 hrs, $15 compensation). Once participants have been seated in a private study room, research staff will communicate with the participants primarily using Zoom as an intercom, to speak/interact with participants. Prior to in-person data collection, staff will review the informed consent in person and/or using a Powerpoint/video tool to ensure they understand the study, its risks and benefits, and their rights as research participants. Participants will have the opportunity to ask questions to the research staff, prior to signing the consent document. Following documentation of informed consent, participants will complete baseline measures to confirm eligibility, have their blood pressure and heart rate checked, provide a urine sample that will be tested for cotinine level (to confirm current smoking status) and pregnancy (women only), and provide a exhaled breath carbon monoxide (eCO) sample. Age will be verified by asking participants to provide some form of identification that includes a date of birth. Photos of participant cigarette packs will be taken. All study procedures will be reviewed/practiced using approved measures and/or Powerpoint/video-based tools. Participants will complete the Minute Discounting Task and finally the Balloon Analogue Risk Task (BART). 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=40) is reached.

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

Products. Own brand tobacco cigarettes will be purchased locally following enrollment by VCU approved staff. For all

other sessions we will provide ECIG liquid at 0 mg/ml, 6 mg/ml, 15 mg/ml, or 30 mg/ml; nicotine and an “open system” ECIG (e.g., Kanger Sub Box Mini C; ECIG device modified by Project 1 team) set to 30 watts. All liquids used will be unflavored and unsweetened. ECIG puffs will be limited to 2 seconds in duration for all of these sessions using hardware and/or a computer program. Own brand cigarette puffs will be allowed to vary in duration (not controlled).

Procedure. The first four sessions will be identical, except for the product given to the participant. The fifth session will be their own brand session. This session will end early, as described below.

Each session, participants will be asked to refrain from tobacco/nicotine use for ≥12 hours and drinking caffeinated beverages for 1 hour prior to their scheduled session with verification of tobacco/nicotine use status upon arrival at the laboratory for each session. More specifically, upon arrival at the laboratory for each session, participants’ breath eCO will be measured to ensure compliance with the overnight abstinence criteria (eCO must be either < or equal to half of the eCO [ppm] that the participant had at the in-person screening visit, or, if 10 ppm or less at screening, it must be equal to or less than 5 ppm before a session can begin). We are no longer requiring 1-hr food abstinence prior to each session as this design detail was originally included to reduce the impact of a recent meal/caloric intake on primary outcomes/participant responding. We reconsidered this design detail in consultation with our study timeline and other protocols ongoing among our research team and decided that this food abstinence requirement likely has less impact than that from caffeine consumption on our primary outcomes and is more burdensome to participants. Research staff will use Zoom, as an intercom to communicate with participants whenever possible during sessions.

At the start of the session, participants will be asked about symptoms experienced since last visit and their use of other substances in their ECIG. Answers given about respiratory and gastrointestinal symptoms will be compared to the participants’ previous answers, and if any symptoms have become more frequent or more severe, Dr. Lipato will be asked to review the symptoms. In some cases, we may contact Dr. Lipato to determine if a session can proceed.

Next, participants will have their breath tested (eCO) to assess compliance and physiologic data collection will begin. We will check blood pressure once at the beginning of the session and again at the end. Heart rate will be measured continuously throughout the session.

Approximately five minutes after session onset, participants will sample the session-specific product (4 puffs) followed by a 60-minute rest period. During this time participants will not be allowed to eat or drink outside beverages but we will provide water to drink and they are invited to use their phone, read books/magazines, or watch movies that we provide to them.

After the rest period, participants will complete baseline subjective measures 1 to assess tobacco abstinence symptoms. Immediately after subjective measures 1, two DPTs (session specific DPT, CP-DPT) will be completed. The DPTs take approximately 10 minutes to complete. Then the PRT will begin, which lasts for 30 minutes. Subjective measures 2 begins at 30 minutes post-PRT start. This should take approximately 5 minutes. After this participants will start the 2nd 60-minute rest period.

After the rest period, participants will complete subjective measures 3. This should take about 5 minutes. Then participants will start the CP-PRT, which lasts for 30 minutes. Subjective measures 4 begins at 30 minutes post-CP-PRT start.

When the CP-PRT and Subjectives measures 4 are completed, physio data collection will end and participants will be paid for their time. The study procedures for sessions 1 – 4 should take no more than 220 minutes or 3 hours and 40 minutes.

For the 5th session, participants will experience the same procedures except they will not complete the CP-DPT or CP-PRT. Thus study procedures for the 5th session should take no more than 185 minutes or 3 hours 5 minutes.

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

Session Timeline:
0m – eCO Check; Physiologic data collection begins, additional questions asked.
5m – 4 sample puffs
10m – Begin 60m rest period
70m – Subjectives measure 1
75m – DPTs – 2: session specific DPT, CP-DPT with their own brand cigs
85m -- PRT – 30 min
115m -- PRT completed; Subjectives measure 2
120m – Begin 60m rest period
180m – Subjectives measure 3
185m -- own brand session STOP
OR
185m – CP-PRT – 30 min
215m – CP-PRT completed; Subjectives measure 4
220m – End session

Product administration will consist of 4 sample puffs at the beginning of each session. Four behavioral tasks will be performed (DPTs, CP-DPT, PRT, and CP-PRT) for sessions 1 – 4. The PRT and CP-PRT behavioral tasks may yield additional puffs from a session specific ECIG or their own brand cigarette. The CP-PRT and CP-DPT will not be performed in the own-brand session (session 5) but participants will be asked to complete the remaining two behavioral choice tasks (DPT and PRT). See the Behavioral Measures section below for more details.

Three months following the final in-person session, participants will be administered one follow- up survey via phone (verbally administered) or email (participant completes survey online) regarding their cigarette and e-cigarette use behaviors ('Follow-Up Survey').

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). We will also take pictures of participant's own brand cigarettes. 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 be obtaining baseline physiological measures including: eCO and HR/BP. eCO will be assessed via a BreathCO monitor (Vitalograph, Lenaxa, KS). HR/BP will be measured and saved electronically using software and equipment that sounds an alarm if safety parameters are exceeded (Model 506, Criticare Systems).

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 participants 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. Prior experience suggests earnings average approximately $23 per participant. A maximum of $40 will be dispensed from the earnings from this task. Data is collected via Inquisit 5 Lab. The data file is stored locally, under a username and password protected windows profile. It is then copied to secure storage locations (such as Ironkey or R-Drive) after each session.

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

Follow-up measures. Follow-up measures re-assess history and patterns of tobacco use, nicotine dependence/craving that were measured at baseline as well as some additional dependence measures specific to e-cigarettes.

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 four behavioral choice tasks (Progressive Ratio Task, Cross Product-Progressive Ratio Task, Drug Purchase Task, and Cross Product-Drug Purchase Task).

The Progressive Ratio Task (PRT) requires participants to click on a button on a computer to earn puffs of the session-specific ECIG or their own brand cigarettes. Ten key presses are required to earn the first puff, and this number is increased by 30% for each subsequent puff. Once the participant declines to press the button for five minutes then the PRT is considered complete. PRT outcome measures are 1) breakpoint PRT (maximum number of key presses completed to earn a puff), 2) number of puffs self-administered, and 3) latency (sec) to initiate key pressing. Data is collected via a software program created using Python. The data file is stored locally, under a username and password protected profile. It is then copied to secure storage locations (such as Ironkey or R-Drive) after each session.

The Cross Product-Progressive Ratio Task (CP-PRT). The CP-PRT asks the participants to perform work, in the form of key presses for puffs of a condition-specific product or own brand cigarette. Using a concurrent schedule (Audrain-McGovern et al., 2015, 2014; Perkins et al., 1994; Perkins et al., 2002), participants are told that they can switch from working for one product or the other as often as they wish. Participants are instructed to press either a “A” key (condition-specific ECIG) or “L” key (own brand cigarette). Consistent with relative reinforcement paradigms, the reinforcement schedule for the session-specific product remains constant at a fixed ratio FR-25 (25 presses achieved to earn a point) while the reinforcement schedule for the own brand cigarettes increases by 25 space bar presses over 10 trials, such that 25, 50, 75, 100, 125, 150, 175, 200, 225, and 250 presses are required to earn a puff (similar to Audrain-McGovern et al., 2015, 2014; Bickel et al., 2000; Epstein et al., 2007). Participants will be randomized to either receive the earned cigarette or ECIG puffs first. Cross-PRT outcome measures are 1) Breakpoint or the highest trial (out of 10 trials) that was completed for own brand cigarette puffs. Data is collected via a software program created using Python. The data file is stored locally, under a username and password protected profile. It is then copied to secure storage locations (such as Ironkey or R-Drive) after each session.

The Drug Purchase Task (DPT) assesses hypothetical tobacco product purchasing behaviors for the session specific ECIG (assessed at sessions 1-4) and own brand CIG (assessed during the own brand session). The outcomes from the DPT include the breakpoint (highest price participants were willing to pay), elasticity (change in amount purchased as price increases), Omax (highest amount individuals paid in any choice, i.e., maximum value of price*quantity), Pmax (the price associated with Omax), and intensity (amount “purchased” when the price is zero/free). Data is collected via REDCap survey and stored under username/password with specific access per user.

The Cross Product (CP)-DPT assesses cross-product purchasing behaviors (assessed at sessions 1-4) between session-specific ECIG products offered at a fixed amount and own brand cigarettes offered at varying prices ($0-20.48). The main outcome for the CP-DPT is cross-price elasticity, or the extent to which purchasing of the session-specific ECIG increases when the price of own brand cigarettes increase. Both the DPT and CP-DPT tasks are programmed to end early if participants report zero consumption for assessed products. Estimated time per measure is <3 min, and each measure will only be completed once per session. Data is collected via REDCap survey and stored under username/password with specific access per user.

Subjective measures. Repeatedly within each condition we will use the Minnesota Nicotine Withdrawal Scale, the

Direct Effects of Nicotine Scale, the Direct Effects of Vaping Scale, the Generalized Labeled Magnitude Scale and the Labeled Hedonic Scale to measure tobacco abstinence symptoms and product assessment before and after each behavioral measure. We will also ask a validation question at the end of each session, “Do you think there was nicotine in the product you used today?”. Data is collected via REDCap survey and stored under username/password with specific access per user.

Additional Detail Regarding Product Use. Participants are not expected to consume all of the liquid that is loaded into the ECIG device for each session. Their product exposure will be limited to the 4 test puffs at the beginning of the session and puffs that they may take as part of the PRT (no puff limit provided; self-directed by the participant) and CP-PRT (limited to a maximum of 10 puffs; self-directed by the participant). We do not expect participants to take more than 40 puffs across the entire session/tasks (~3.5 hours) based on our experience with these tasks and ECIG conditions used previously. Of note we have another study in progress with similar task/puff requirements using a similar nicotine concentration liquid with no adverse effects noted among our participants.

Data analysis. Subjective, physiological, DPT, CP-DPT, PRT, and CP-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. Unexpected between group differences will be considered as potential covariates in the primary analysis (see Evans et al., 2006). Statistical analyses may utilize regression, ANOVA, or mixed linear models. Adjustments for sphericity violations and post-hoc testing using Tukey's HSD or planned contrasts with Bonferroni corrections will be used (Keppel, 1991). Based upon the type and amount of missing data, we may use accepted techniques such as multiple imputation (Allison, 2001).

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

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

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

   We are no longer requiring 1-hr food abstinence prior to each session as this design detail was originally included to reduce the impact of a recent meal/caloric intake on primary outcomes/participant responding. We reconsidered this design detail in consultation with our study timeline and other protocols ongoing among our research team and decided that this food abstinence requirement likely has less impact than that from caffeine consumption on our primary outcomes and is more burdensome to participants.

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

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

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

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

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Informed Consent	P3 FLUX_Informed Consent_12.07.2022_CLEAN.pdf	0.29	2/27/2023 12:23 AM	Rebecca Scholtes	Consent/Assent/Information Sheet	Yes
View	Consent - Tool	P3FLUX_Consent_Presentation_12.07.2022_CLEAN.pptx	0.13	12/7/2022 2:37 PM	Rebecca Scholtes	Other	Yes
View	Text, Email, Call Scripts	Phone_e-mail_text scripts_CLEAN__12.07.2022.docx	0.19	12/7/2022 2:35 PM	Rebecca Scholtes	Other	Yes
View	COVID-19 Questions	NO LONGER USING_COVID_Questions_P3_12.07.2022.docx	0.06	12/7/2022 2:33 PM	Rebecca Scholtes	Other	No
View	Information about Blood Pressure	BP results P3 flux 8.22.2022.docx	0.01	8/22/2022 11:43 AM	Rabia Imran	Other	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	P3 Flux Advertisement for CSTP Website	P3 FLUX Description for CSTP Website_CLEAN_03.30.2022.docx	0.05	4/13/2022 10:36 AM	Rebecca Scholtes	Recruitment/Advertising	Yes
View	Referral Program Card Template	P3_Referral program card_1.13.2022.docx	0.01	1/14/2022 11:49 AM	Caroline Cobb Amey	Recruitment/Advertising	Yes
View	Baseline Self Report Physio Measures	P3- FLUX_Baseline forms All_5.21.2021_CLEAN.docx	0.14	5/24/2021 2:01 PM	Rebecca Scholtes	Research Measure	Yes
View	Follow-up Survey	P3-FLUX-Follow-up_05.21.2021_CLEAN.docx	0.11	5/24/2021 1:59 PM	Rebecca Scholtes	Research Measure	Yes
View	CP-DPT & DPT - Tool	DPT_CDPT presentation_04.26.2021_CC.pptx	0.03	4/26/2021 4:36 PM	Rebecca Scholtes	Other	Yes
View	DPT/CP-DPT - Tool VIDEO	DPT_CDPT presentation_04.26.2021_CC.mp4	0.02	4/26/2021 4:35 PM	Rebecca Scholtes	Other	Yes
View	Drug Purchase Tasks (DPT)	P3-FLUX-Drug Purchase Tasks_04.26.2021_CLEAN.docx	0.03	4/26/2021 12:23 PM	Rebecca Scholtes	Research Measure	Yes
View	Puff Limiting Software Details	P3-Flux Puff Limiting Software.docx	0.01	3/19/2021 3:54 PM	Caroline Cobb Amey	Other	Not Applicable
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View	Expired Air CO Manual	CO Monitor Manual.pdf	0.01	3/6/2020 12:27 PM	Rebecca Scholtes	Other	Not Applicable

Project Details

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

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

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

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

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

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

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

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

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

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

Behavioral Intervention/Task Details

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

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

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

1. * **Describe the duration of the social/behavioral intervention, task, or environmental manipulation:**
   This study has a total of five sessions. The first four sessions are about 3 hours and 40 minutes. The final session is slightly shorter, lasting about 3 hours.

2. * **Describe any potential harms or discomforts that participants could experience during the intervention activity:**
   Physical Risks:
   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. You may experience mild frustration while completing some of the study-related tasks.
   3. 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.
   4. The e-cigarette liquid that we give you may contain more nicotine than you are used to, although some e-cigarette users report using these liquids. Inform the study staff immediately if you experience any discomfort
   5. You may also experience side effects from products that contain nicotine such as acute increases in heart rate and blood pressure, sweating, lightheadedness, dizziness, nausea, and nervousness. These side effects are unlikely in individuals who use cigarettes regularly.
   6. The Centers for Disease Control and Prevention advises that e-cigarette, or vaping products are unsafe for youths, young adults, or women who are pregnant. Adults who do not currently use tobacco products should not start using e-cigarette, or vaping, products. If you use e-cigarette products, monitor yourself for the below symptoms and promptly seek medical attention if you have concerns about your health.
   a. Some people who use e-cigarettes have reported experiencing seizures. Some of these individuals reported a prior history of seizures or using other substances at the same time as their e-cigarette.
   b. In some cases, e-cigarette use has led to respiratory illnesses such as difficulties breathing, shortness of breath, cough, and/or chest pain before hospitalization. In some cases, e-cigarette use has led to death, although most of these cases have been related to vaping THC.
   c. In some cases, e-cigarette use has been associated with symptoms of mild to moderate gastrointestinal illness such as nausea, abdominal pain, vomiting, diarrhea, fevers or fatigue.
   7. The use of e-cigarettes may include other side effects/risks such as a sore or scratchy throat and headache.
   8. 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.
   9. The researchers will let you know about any significant new findings (such as additional risks or discomforts) that may make you change your mind about participating in the study.

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

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

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

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

Sample Collection Details

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

2. * **If Other, please describe the type of sample being collected:**
   Upon arrival at the laboratory for the research session, participants' eCO will be measured to ensure compliance with the overnight abstinence criteria. Samples will not be stored.

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

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

   - The procedures that will be followed to collect the sample
   - The role(s) of the individuals who will collect the sample
   - The volume/size range of the sample
   - The timing and frequency of sample collection
   Urine will be collected during the baseline screening to test for recent nicotine exposure and for current pregnancy for women. About 30 mL is required for testing purposes, participants may provide more but it is not required. 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 genetic analyses be conducted on any of the samples:**
   - ○ Yes
   - ● **No**

Active Internet Data Collection

1. * **Describe the platform/technology chosen for collecting the data and transmitting data securely over the internet. If proposing a non-VCU approved platform, give the rationale for selecting the technology instead of a VCU-approved platform.**
   Screening (baseline), session, and follow-up data will be collected and stored using the REDCap database which is located on a category one secured database at VCU. Viewing of the REDCap project will be restricted to personnel associated with this protocol.

2. * **Describe how data will be linked or unlinked to identifiers including email addresses, names, and/or IP address.**
   If a participant enrolls in this study, they are given a numeric code (the study ID) that is connected 1) to their consent (i.e., name) via a paper key, 2) added to their registry information (the registry ID), via a separate variable in our administrative forms connected to each registry via an electronic key, and 3) their contact information which use to send the follow-up survey.

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

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

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

3. * **How will you protect your data collection from fraudulent responses:**
   The majority of measures/sessions are completed in the laboratory. Thus, we are able to monitor how participants are answering questions and ask for clarification if an answer conflicts with another answer for example. Only the follow-up survey (which has a participant unique link) is administered outside of the laboratory.

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

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

   For the follow-up forms, the alternative is to complete these forms verbally over the phone.

6. * **Describe how individuals will be able to skip or not answer particular questions. If any questions are mandatory, provide justification.**
   Participants can skip other questions administered during the baseline session except for those required for eligibility purposes.

   During study sessions, we will require responses to the symptoms experienced since last study visit questions. This allows study staff can assess a participant's recent symptoms to continue with the scheduled sessions. If a participant does not want to answer a question, they can inform study staff who can note this and remove answers (we require responses in subjective questionnaires as we find if we do not this leads to missing questions by mistake).

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

Secondary Data/Specimen Details

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

   a. Identify where the data/specimens will come from (e.g., another researcher's registry, pathology lab, commercial source, medical records, etc.); and
   b. List what types of specimens will be obtained (when applicable); and/or
   c. List all data elements that will be obtained (when applicable). A data collection form or other documentation may be uploaded and referenced here.
   1. CSTP Overall Screening and Registry and the Behavioral Health Research Laboratory Screening and Registry will be used to pre-screen/determine initial eligibility for participants.

   2. No data will be obtained from these protocols or transferred to the current protocol. Staff from the two registry projects will review participant responses and document on an administrative form whether they meet eligibility requirements for the current protocol.

   3. No data will be obtained but current staff on this protocol will access the administrative form of either registry and use this information to contact potentially eligible participants. This includes accessing contact information (name, phone, email address), provided by participants within each respective registry survey/REDCap Project. Eligibility information and contact information will not need to be transferred or exported from either project.

   The staff of HM20018290 who contact participants will also be staff on HM20002567/HM20007677. Please note, we are filling out the eligibility admin form as registry staff (not staff on this study). Participants who join the registry and complete the screening survey are evaluated for potential eligibility across all currently approved projects by approved registry staff. Registry staff responses regarding their eligibility for the present study are used to determine whether individuals are contacted for an in-person screening appointment where all eligibility criteria are evaluated again

2. * **Describe whether any agreement exists between you and data/specimen provider that states you will never have access to the ability to identify the participants (i.e. access to identifiers or the code key) and that you will not attempt to re-identify individuals.**
   Each registry contains identifying information such as names/phone numbers/email addresses.

   If a participant enrolls in this study, they are given a numeric code (the study ID) that is connected to their registry information (the registry ID), via a separate variable in our administrative forms connected to each registry. Thus each participant will have a registry ID as well as a study ID (specific to this protocol). Adding the study ID from this usage protocol to a registry is a form of an electronic key, and as it will be a separate variable in an administrative form, it can be deleted once the usage protocol is complete. The purpose of this link between the registry and this usage protocol is to help us keep track of which participants are participating in which usage protocol. No data from this usage protocol will be transferred to the registry (other than the study ID).

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

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

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

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

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

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

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View	Informed Consent	P3 FLUX_Informed Consent_12.07.2022_CLEAN.pdf	0.29	2/27/2023 12:23 AM	Rebecca Scholtes	Consent/Assent/Information Sheet	Yes

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View	Text, Email, Call Scripts	Phone_e-mail_text scripts_CLEAN__12.07.2022.docx	0.19	12/7/2022 2:35 PM	Rebecca Scholtes	Other	Yes
View	COVID-19 Questions	NO LONGER USING_COVID_Questions_P3_12.07.2022.docx	0.06	12/7/2022 2:33 PM	Rebecca Scholtes	Other	No
View	Information about Blood Pressure	BP results P3 flux 8.22.2022.docx	0.01	8/22/2022 11:43 AM	Rabia Imran	Other	Yes
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HM20018290 - Caroline Cobb Amey
Effects of E-Cigarette Nicotine Delivery on Abuse Liability in Smokers (Project 3 Flux Study)

Costs to Participants

1. * **Select all categories of costs that participants or their insurance companies will be responsible for:**
   - [x] **Participants will have no costs associated with this study**
   - [ ] Study related procedures that would be done under standard of care
   - [ ] Study related procedures not associated with standard of care
   - [ ] Administration of drugs / devices
   - [ ] Study drugs or devices
   - [ ] Other

Compensation

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

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

   1. Eligible participants = Total potential compensation is $55 from the in-person screening and $510 from session/follow-up procedures (up to $565 in total across the entire study).

   Ineligible participants = $15 for attending the in-person screening.

   If lab parking is not available, participants are reimbursed for parking expenses only for any in-person sessions.

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

   2. All payments will be in the form of cash with the exception of the follow-up survey and the referral card payments (Amazon gift card via email).

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

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

2. **If compensation will be pro-rated, explain the payment schedule.**
   Eligible & ineligible participants will be paid $15 for their responses/in cash at the completion of the in-person screening.

   Eligible participants will have an opportunity to complete a behavioral measure (BART) at the in-person screening. They can earn up to $40.

   If enrolled, compensation will be $75 session 1, $100 for session 2, $100 for session 3, $100 for session 4, and $125 for session 5.

   Participants will receive $10 for the follow-up survey.

   This makes for total potential compensation of $55 from the in-person screening and $510 from session/follow-up procedures (up to $565 in total across the entire study).

   If a session must be discontinued for reasons beyond the control of the participant, the participant will be paid for the time spent complying with study conditions before the session began ($15) and also the time spent in the laboratory ($15/hour).

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

Contingency Plan

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

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

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

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

HM20018290 - Caroline Cobb Amey
Effects of E-Cigarette Nicotine Delivery on Abuse Liability in Smokers (Project 3 Flux Study)

Research Complete

[redacted] Progress:
[redacted]L SETUP
[redacted]GROUND, RATIONALE & GOALS
[redacted]EARCH 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

HM20018290 - Caroline Cobb Amey
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Consent Process

1. * List all consent groups:

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

2. Upload any consent / assent documents:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Informed Consent	P3 FLUX_Informed Consent_12.07.2022_CLEAN.pdf	0.29	2/27/2023 12:23 AM	Rebecca Scholtes	Consent/Assent/Information Sheet	Yes
View	Consent - Tool	P3FLUX_Consent_Presentation_12.07.2022_CLEAN.pptx	0.13	12/7/2022 2:37 PM	Rebecca Scholtes	Other	Yes
View	Text, Email, Call Scripts	Phone_e-mail_text scripts_CLEAN__12.07.2022.docx	0.19	12/7/2022 2:35 PM	Rebecca Scholtes	Other	Yes
View	COVID-19 Questions	NO LONGER USING_COVID_Questions_P3_12.07.2022.docx	0.06	12/7/2022 2:33 PM	Rebecca Scholtes	Other	No
View	Information about Blood Pressure	BP results P3 flux 8.22.2022.docx	0.01	8/22/2022 11:43 AM	Rabia Imran	Other	Yes
View	P3 Flux Advertisement for CSTP Website	P3 FLUX Description for CSTP Website_CLEAN_03.30.2022.docx	0.05	4/13/2022 10:36 AM	Rebecca Scholtes	Recruitment/Advertising	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Referral Program Card Template	P3_Referral program card_1.13.2022.docx	0.01	1/14/2022 11:49 AM	Caroline Cobb Amey	Recruitment/Advertising	Yes
View	Baseline Self Report Physio Measures	P3- FLUX_Baseline forms All_5.21.2021_CLEAN.docx	0.14	5/24/2021 2:01 PM	Rebecca Scholtes	Research Measure	Yes
View	Follow-up Survey	P3-FLUX-Follow-up_05.21.2021_CLEAN.docx	0.11	5/24/2021 1:59 PM	Rebecca Scholtes	Research Measure	Yes
View	CP-DPT & DPT - Tool	DPT_CDPT presentation_04.26.2021_CC.pptx	0.03	4/26/2021 4:36 PM	Rebecca Scholtes	Other	Yes
View	DPT/CP-DPT - Tool VIDEO	DPT_CDPT presentation_04.26.2021_CC.mp4	0.02	4/26/2021 4:35 PM	Rebecca Scholtes	Other	Yes
View	Drug Purchase Tasks (DPT)	P3-FLUX-Drug Purchase Tasks_04.26.2021_CLEAN.docx	0.03	4/26/2021 12:23 PM	Rebecca Scholtes	Research Measure	Yes
View	Puff Limiting Software Details	P3-Flux Puff Limiting Software.docx	0.01	3/19/2021 3:54 PM	Caroline Cobb Amey	Other	Not Applicable
View	Consent - Tool VIDEO	No_Longer_Using_This_Tool.docx	0.03	1/26/2021 11:37 AM	Rebecca Scholtes	Other	No
View	Facebook Advertisements	facebook ads_01.25.2021.docx	0.01	1/26/2021 10:16 AM	Rebecca Scholtes	Recruitment/Advertising	Yes
View	Combined PRT/CP-PRT - Tool	1.19_21_combinedPRT_instructions..pptx	0.02	1/25/2021 9:20 PM	Rebecca Scholtes	Other	Yes
View	Progressive Ratio Task (PRT)	PRT_FLUX_V3_1.22.21.pdf	0.03	1/25/2021 9:19 PM	Rebecca Scholtes	Research Measure	Yes
View	Subjective Measures	P3-FLUX-Session Subjective Measures_01.25.2021_CLEAN.doc	0.05	1/25/2021 4:45 PM	Rebecca Scholtes	Research Measure	Yes
View	CP-PRT - Tool	No_Longer_Using_This_Tool.docx	0.02	9/30/2020 1:48 PM	Rebecca Scholtes	Other	No
View	PRT - Tool	No_Longer_Using_This_Tool.docx	0.02	9/30/2020 1:47 PM	Rebecca Scholtes	Other	No
View	Subjective Measures - Tool VIDEO	Subjective Measures presentation_09.02.2020.mp4	0.01	9/9/2020 10:54 PM	Rebecca Scholtes	Other	Yes
View	Subjective Measures -Tool	Subjective Measures presentation_09.02.2020.pptx	0.02	9/9/2020 10:38 PM	Rebecca Scholtes	Other	Yes
View	Cross Product Progressive Ratio Task (CP-PRT)	CP_PRT_Flux_V2_08.04.2020.pdf	0.02	8/17/2020 11:46 AM	Rebecca Scholtes	Research Measure	Yes
View	Flux Advertisements	FLUX_Combined Ads_07.20.2020_V3_CLEAN.pdf	0.05	7/20/2020 10:32 AM	Rebecca Scholtes	Recruitment/Advertising	Yes
View	CSTP Registry Consent Document	CSTP_Consent and screening_registry questions updated 4.29.19 CHANGES ACCEPTED.pdf	0.01	4/2/2020 3:36 PM	Rebecca Scholtes	Consent/Assent/Information Sheet	Not Applicable
View	BHRL Registry Consent Document	HM20007677 Consent Form_06.21.2019_CLEAN.pdf	0.01	4/2/2020 3:33 PM	Rebecca Scholtes	Consent/Assent/Information Sheet	Not Applicable
View	Presession Symptom Questions	P3-FLUX-Presession symptom Checklist-01.09.2019.docx	0.01	4/2/2020 12:47 AM	Rebecca Scholtes	Research Measure	Yes
View	Barnes Biosketch	P3 Barnes biosketch 06.22.17.FINAL.docx	0.01	4/1/2020 11:23 PM	Rebecca Scholtes	CV/Biosketch	Not Applicable
View	Lipato Biosketch	Lipato Biosketch_10.5.16.docx	0.01	4/1/2020 11:22 PM	Rebecca Scholtes	CV/Biosketch	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Caroline Cobb (Amey) CV	Curriculum Vitae_Cobb_December 2019.docx	0.01	3/9/2020 11:16 AM	Caroline Cobb Amey	CV/Biosketch	Yes
View	Baseline Discounting Task - MDT	P3_FLUX_Discounting Task_11.7.2018.pdf	0.01	3/6/2020 1:26 PM	Rebecca Scholtes	Research Measure	Yes
View	Baseline Risk Taking Task - BART	P3_FLUX_BART_screenshot.11.8.2018.pdf	0.01	3/6/2020 1:26 PM	Rebecca Scholtes	Research Measure	Yes
View	U54 Project 3 Grant Docs	U54_Project 3 only docs.pdf	0.01	3/6/2020 12:51 PM	Rebecca Scholtes	Funding Proposal	Not Applicable
View	CSTP Parking Map	CSTP Parking Map .docx	0.01	3/6/2020 12:28 PM	Rebecca Scholtes	Other	Yes
View	Criticare HR/BP Manual	Criticare_Vitalcare_506N3_-_Service_manual.pdf	0.01	3/6/2020 12:28 PM	Rebecca Scholtes	Other	Not Applicable
View	Expired Air CO Manual	CO Monitor Manual.pdf	0.01	3/6/2020 12:27 PM	Rebecca Scholtes	Other	Not Applicable

HM20018290 - Caroline Cobb Amey
Effects of E-Cigarette Nicotine Delivery on Abuse Liability in Smokers (Project 3 Flux Study)

Consent Plan Complete

[redacted] Progress:
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[redacted]ARCH PLAN
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⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
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Click Continue below to go to the next section

Risks, Discomforts, Potential Harms and Monitoring

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

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

   See the help text for additional guidance.

   There are few risks associated with this study.

   1. 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.

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

   3. 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.

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

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

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

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

   8. There is some risk of loss of confidentiality.

   There is little available data on the range of power settings (in Watts) and liquid concentrations that ECIG users use. One paper described data on power and liquid settings for 165 adult users in California, which showed a median power setting of 204.5 W, although the authors note that many participants were not able to accurately report their power settings. In the same study, the median liquid concentration was 6.0 mg/ml nicotine with a range of 0 - 30.0 mg/ml. Data collected in an ongoing study in the CSTP for N = 44 shows an average power setting of 55.3 W (range = 6.8 - 204 W) and a mean liquid concentration of 7.6 mg/ml nicotine (range = 3 - 18 mg/ml). We have conducted a variety of ECIG studies previously in the CSTP with liquid that is 36 mg/ml nicotine. Finally, information from e-cigarette forums indicates that individuals are using both low and high nicotine liquids (35 - 50 mg/ml, for example) in "third generation", variable-wattage devices like the one we are proposing to use in this study.

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. These risks are minimized by limited exposure to ECIGs in study sessions. We do not anticipate participants taking more than 40 puffs per session.

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. Partcipants are expected to take no more than 40 puffs of either their own brand CIG or the session-specific ECIG at each session. Participants are informed about recent reports of ECIG-related respiratory illnesses and are informed that the CDC has advised people to stop vaping. Participants are also advised to monitor themselves for symptoms and to seek medical attention if they have concerns. In addition, we will ask about respiratory and gastrointestinal symptoms at screening and before each session begins. Answers given at the beginning of each session will be compared to the participants' previous answers, and if any symptoms have increased, Dr. Lipato will be asked to review the symptoms. In some cases, we may contact Dr. Lipato to determine if a session can proceed.

We recruit individuals aged 18 + who use nicotine-containing products at similar or higher daily/weekly frequencies that they would be exposed in the laboratory setting. For example, our cigarette smokers must report smoking at least 5 cigarettes per day or at least 1 cigarette/day and at least weekly use of another inhaled tobacco product and a positive cotinine cassette test to verify nicotine use. Their laboratory-based product exposure will be limited to the 4 test puffs at the beginning of the session and puffs that they may take as part of the PRT (no puff limit provided; self-directed by the participant) and CP-PRT (limited to a maximum of 10 puffs; self-directed by the participant). We do not expect participants to take more than 40 puffs across the entire session/tasks (~3.5 hours) based on our experience with these tasks and ECIG conditions used previously. Considering only a minimum of 4 tobacco product puffs are required (other puffs are self-directed and/or restricted in number) our protocol ensures that study-related nicotine/tobacco exposure is similar to or less than what participants may expose themselves to as part of their ordinary life.

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

Our sessions and surveys are optimized in length to make them as short as possible while ensuring collection of primary study outcomes. We believe 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.

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

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 or at a session will be provided with a blood pressure information sheet by the research staff (see study document). This sheet will be provided at the first instance of elevated blood pressure observed during the study.

   Research personnel are trained to alert the research nurse if heart rate continually exceeds 120 beats per minute, if systolic BP continually exceeds 160 mm Hg, or if diastolic BP continually exceeds 100 mm Hg. Individuals whose heart rate and/or BP levels remain elevated will be monitored by the research nurse and if, necessary, emergency responders will be notified. Emergency medical coverage will be available via the emergency room that is 1.5 miles from the CSTP.

5. * **Describe criteria for when the investigator would withdraw an individual participant from the study; such as safety or toxicity concerns, emotional distress, inability to comply with the protocol, etc.:**
   Participants may be withdrawn from the study if the PI or study nurse has any safety concerns (such as high blood pressure or heart rate) during sessions.

   The PI/research nurse and/or Medical Monitor will be consulted/notified via phone/email specifically concerning high

blood pressure observations that occur during any study session to determine whether a participant should remain in the study.

If a participant does not comply with the 12-hour tobacco/nicotine abstinence requirement (which can be difficult for some participants), we allow participants to re-schedule a session. We allow multiple attempts, but do not have a specified number of attempts that are allowed, as it depends on the circumstances of each participant.

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

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

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

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

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

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

See the help text for additional guidance.

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

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

3. When and how frequently monitoring will occur:
Any adverse events and protocol deviations/violations that occur during the study sessions will be monitored and documented by the research staff and communicated as soon as possible to PI/medical monitor for review/response. We will follow VCU IRB reporting requirements for all adverse events and protocol deviations/violations that may occur. We also will review all of the items listed in #2 in a summary report annually.

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

Privacy

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

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

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

Instructions for this page:

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

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

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

Read the entire page before filling out the form.

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

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

- [ ] Other protections not listed in this question – describe below
- [x] **N/A – study has no group interventions or interactions**

3. * Protections when conducting remote interventions or interactions (e.g. phone, text, email, video-conference, tele-health, online, etc.):

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

4. * Protections when mailing study materials to/from participants:

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

5. * Protections when analyzing or disseminating study data *Applicable to all studies*:

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

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

Participants' privacy and comfort will be addressed throughout the course of 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. We will use Zoom (like an intercom) to communicate with participants from outside of the session room, the participants' name will not be entered into Zoom. We will use a password-protected zoom session. Participants will be informed that they

may withdraw from the research study should they find any research procedures unacceptable. All participants and data will be treated with professional standards of confidentiality.

Data are identified by numeric code only and stored under double lock. Participants' names are not directly linked to data, with the exception of the contact information we request to send the follow-up survey. 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 paper key is maintained in the study binder so that we can demonstrate that a particular data set is associated with a particular consent document.

An electronic key is maintained within the Phone/Web screening data REDCap projects and the study project where participant contact information is stored for follow-up survey purposes. This key connects participant contact information to their unique numeric code for this protocol so that we can communicate effectively with participants as well as reduce the number of places/REDCap projects where participant contact information is stored. No data from the current protocol (HM20018290) is stored in the Phone/Web screening data protocols other than the unique numeric code. This electronic key will be deleted when data collection for the study has been completed.

The paper 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. It describes how the study's research materials (data, specimens, records, etc.) are protected from unauthorized access.

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

Read the entire page before filling out the form.

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

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

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

4. * **Protections for computers and research devices/apps that are provided to participants for use in the study and taken out of the lab (i.e., giving participants a phone or iPad to take home, wearable trackers, apps, etc.):**

- [x] **Transferring data promptly from the device/app given to the participant to a VCU storage location**
- [x] **Setting strong passwords on computers and research devices (when applicable) that leave VCU with participants**
- [ ] Device/app set up by VCU Information Security
- [ ] When providing devices or mobile apps to children, informing parents about the settings and how to manage them (if applicable), internet access, and any other installed apps on the device
- [ ] Other protection not listed in this question – describe the device/app and protection below
- [ ] N/A – no computers or devices/apps being provided for participant use outside the lab

5. * **Protections for email/online communications**

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

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

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

Electronic records will be stored in REDCap made available only to those personnel in the study through the use of access controls and encryption (e.g., Ironkey and VCU File Locker). Note that VCU File Locker is not used as a primary source of data transfer. Participant computers are not equipped with R-Drive access for data safety. In the unlikely case that other data transfer methods (Ironkey or R-Drive) are not available, VCU Filer Locker may be used to transfer data. Generally, data, outside of REDCap, is transferred via Ironkey from participant computers to lab-staff computers where it is stored on the R-Drive.

Identifiers will be removed from study-related data (with the exception of contact information that we ask for as part of the follow-up survey), and data will be coded with a key stored in a separate, secure location in a locked cabinet. All web-based surveys will have data secured via passwords. De-identified data will be transferred to secure servers that are password protected for data cleaning and analysis. No data will be stored under any other departments.

Some data (self-report, pictures of own brand product, and physiological) are recorded using software separate from REDCap. These data are stored on password protected computers and backed-up on secure datakeys that require a password (IronKey).

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

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

BART data (see, 'Baseline Discounting Task - BART' document) is collected at baseline or in-person screening visits only via Inquisit 5 Lab. The data file is stored locally, under a username and password protected profile. It is then copied to secure storage locations (such as Ironkey or R-Drive) after each session.

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

PRT and CP-PRT data are collected at study sessions via a program written in Python by lab staff. The data file is stored locally, under a username and password protected profile. It is then copied to secure storage locations (such as Ironkey or R-Drive) after each session.

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

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

- [x] **Names**
- [x] **Geographic Locators Below State Level**

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

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

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

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

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

    See the help text for guidance.
    Data are identified by numeric code only and stored under double lock. Participants' names are not directly linked to data, with the exception of the contact information we request to send the follow-up survey. 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 paper key is maintained in the study binder so that we can demonstrate that a particular data set is associated with a particular consent document. The key and consent documents are stored separately from each other and separately from all data (under double lock). Access to the paper 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 paper 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.

    An electronic key is maintained within the Phone/Web screening data REDCap projects and the study project where participant contact information is stored for follow-up survey purposes. This key connects participant contact information to their unique numeric code for this protocol so that we can communicate effectively with participants as well as reduce the number of places/REDCap projects where participant contact information is stored. No data from the current protocol (HM20018290) is stored in the Phone/Web screening data protocols other than the unique numeric code. This electronic key will be deleted when data collection for the study has been completed.

Data Retention

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

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

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

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

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

6. **If yes, describe at what point and how recordings will be destroyed:**
   We will use unobtrusive audio/video via Zoom of the participants throughout in-person screen and sessions. The in-person screen and sessions will be monitored by research staff via VCU computers (audio/video data is transmitted via internet). The only purpose of utilizing audio/visual monitoring is to effectively and safely communicate with participants while reducing face to face interaction times.

   Live video will be monitored using privacy screens to ensure confidentiality during sessions. Zoom sessions will not be recorded or stored or linked to participant IDs or used for any analysis purpose.

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

Sharing Plan

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

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

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

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

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

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

   ○ Yes
   ● **No**

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

   ○ Yes ● **No**

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

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

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

4. * **Select the way(s) that information or biospecimens (including DNA) may be used 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. VCU IRB studies will be asked more questions about this on a later page)

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

   ('De-identified' means that a linkage/key code exists that links identifiers to data/specimens. When the researcher holds both the data and the key, the VCU IRB considers the subjects to be readily identifiable. Maintaining identifiable data for future research uses is treated by the IRB as a registry. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. VCU IRB studies will be asked more questions about this on a later page)

   ☑ Will use anonymized information or specimens.

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

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

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

Will contribute to an existing registry or repository

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

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

☐ Not sure and will submit an amendment when known

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

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

Will share directly identifiable information or specimens with other researchers.

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

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

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

Will share anonymized information or specimens with other researchers.

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

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

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

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

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

☐ Will not share information/specimens with other researchers.

☐ Not sure and will submit an amendment when known

☐ Other sharing of individual-level information with other researchers

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

☑ **The consent form states that after identifiers are removed, information or specimens could be used for future research studies without additional informed consent from the subject (this is a new element of consent included in consent templates as of May 2018)**

- ☐ The consent form or exempt information sheet is silent about whether/how information or specimens could be used for future research studies.
- ☐ The information or specimens were/will be obtained under a waiver of informed consent, waiver of HIPAA authorization, or an exempt study that did not use an information sheet.
- ☐ Other reason why anonymous use/sharing is not inconsistent with the consent document

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

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

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

- ● **Yes**
- ○ No

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

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

- ● **Yes**
- ○ No
- ○ N/A - No sharing will occur

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

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Informed Consent	P3 FLUX_Informed Consent_12.07.2022_CLEAN.pdf	0.29	2/27/2023 12:23 AM	Rebecca Scholtes	Consent/Assent/Information Sheet	Yes
View	Consent - Tool	P3FLUX_Consent_Presentation_12.07.2022_CLEAN.pptx	0.13	12/7/2022 2:37 PM	Rebecca Scholtes	Other	Yes
View	Text, Email, Call Scripts	Phone_e-mail_text scripts_CLEAN__12.07.2022.docx	0.19	12/7/2022 2:35 PM	Rebecca Scholtes	Other	Yes
View	COVID-19 Questions	NO LONGER USING_COVID_Questions_P3_12.07.2022.docx	0.06	12/7/2022 2:33 PM	Rebecca Scholtes	Other	No
View	Information about Blood Pressure	BP results P3 flux 8.22.2022.docx	0.01	8/22/2022 11:43 AM	Rabia Imran	Other	Yes
View	P3 Flux Advertisement for CSTP Website	P3 FLUX Description for CSTP Website_CLEAN_03.30.2022.docx	0.05	4/13/2022 10:36 AM	Rebecca Scholtes	Recruitment/Advertising	Yes
View	Referral Program Card Template	P3_Referral program card_1.13.2022.docx	0.01	1/14/2022 11:49 AM	Caroline Cobb Amey	Recruitment/Advertising	Yes
View	Baseline Self Report Physio Measures	P3- FLUX_Baseline forms All_5.21.2021_CLEAN.docx	0.14	5/24/2021 2:01 PM	Rebecca Scholtes	Research Measure	Yes
View	Follow-up Survey	P3-FLUX-Follow-up_05.21.2021_CLEAN.docx	0.11	5/24/2021 1:59 PM	Rebecca Scholtes	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	CP-DPT & DPT - Tool	DPT_CDPT presentation_04.26.2021_CC.pptx	0.03	4/26/2021 4:36 PM	Rebecca Scholtes	Other	Yes
View	DPT/CP-DPT - Tool VIDEO	DPT_CDPT presentation_04.26.2021_CC.mp4	0.02	4/26/2021 4:35 PM	Rebecca Scholtes	Other	Yes
View	Drug Purchase Tasks (DPT)	P3-FLUX-Drug Purchase Tasks_04.26.2021_CLEAN.docx	0.03	4/26/2021 12:23 PM	Rebecca Scholtes	Research Measure	Yes
View	Puff Limiting Software Details	P3-Flux Puff Limiting Software.docx	0.01	3/19/2021 3:54 PM	Caroline Cobb Amey	Other	Not Applicable
View	Consent - Tool VIDEO	No_Longer_Using_This_Tool.docx	0.03	1/26/2021 11:37 AM	Rebecca Scholtes	Other	No
View	Facebook Advertisements	facebook ads_01.25.2021.docx	0.01	1/26/2021 10:16 AM	Rebecca Scholtes	Recruitment/Advertising	Yes
View	Combined PRT/CP-PRT - Tool	1.19_21_combinedPRT_instructions..pptx	0.02	1/25/2021 9:20 PM	Rebecca Scholtes	Other	Yes
View	Progressive Ratio Task (PRT)	PRT_FLUX_V3_1.22.21.pdf	0.03	1/25/2021 9:19 PM	Rebecca Scholtes	Research Measure	Yes
View	Subjective Measures	P3-FLUX-Session Subjective Measures_01.25.2021_CLEAN.doc	0.05	1/25/2021 4:45 PM	Rebecca Scholtes	Research Measure	Yes
View	CP-PRT - Tool	No_Longer_Using_This_Tool.docx	0.02	9/30/2020 1:48 PM	Rebecca Scholtes	Other	No
View	PRT - Tool	No_Longer_Using_This_Tool.docx	0.02	9/30/2020 1:47 PM	Rebecca Scholtes	Other	No
View	Subjective Measures - Tool VIDEO	Subjective Measures presentation_09.02.2020.mp4	0.01	9/9/2020 10:54 PM	Rebecca Scholtes	Other	Yes
View	Subjective Measures -Tool	Subjective Measures presentation_09.02.2020.pptx	0.02	9/9/2020 10:38 PM	Rebecca Scholtes	Other	Yes
View	Cross Product Progressive Ratio Task (CP-PRT)	CP_PRT_Flux_V2_08.04.2020.pdf	0.02	8/17/2020 11:46 AM	Rebecca Scholtes	Research Measure	Yes
View	Flux Advertisements	FLUX_Combined Ads_07.20.2020_V3_CLEAN.pdf	0.05	7/20/2020 10:32 AM	Rebecca Scholtes	Recruitment/Advertising	Yes
View	CSTP Registry Consent Document	CSTP_Consent and screening_registry questions updated 4.29.19 CHANGES ACCEPTED.pdf	0.01	4/2/2020 3:36 PM	Rebecca Scholtes	Consent/Assent/Information Sheet	Not Applicable
View	BHRL Registry Consent Document	HM20007677 Consent Form_06.21.2019_CLEAN.pdf	0.01	4/2/2020 3:33 PM	Rebecca Scholtes	Consent/Assent/Information Sheet	Not Applicable
View	Presession Symptom Questions	P3-FLUX-Presession symptom Checklist-01.09.2019.docx	0.01	4/2/2020 12:47 AM	Rebecca Scholtes	Research Measure	Yes
View	Barnes Biosketch	P3 Barnes biosketch 06.22.17.FINAL.docx	0.01	4/1/2020 11:23 PM	Rebecca Scholtes	CV/Biosketch	Not Applicable
View	Lipato Biosketch	Lipato Biosketch_10.5.16.docx	0.01	4/1/2020 11:22 PM	Rebecca Scholtes	CV/Biosketch	Yes
View	Caroline Cobb (Amey) CV	Curriculum Vitae_Cobb_December 2019.docx	0.01	3/9/2020 11:16 AM	Caroline Cobb Amey	CV/Biosketch	Yes
View	Baseline Discounting Task - MDT	P3_FLUX_Discounting Task_11.7.2018.pdf	0.01	3/6/2020 1:26 PM	Rebecca Scholtes	Research Measure	Yes
View	Baseline Risk Taking Task - BART	P3_FLUX_BART_screenshot.11.8.2018.pdf	0.01	3/6/2020 1:26 PM	Rebecca Scholtes	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	U54 Project 3 Grant Docs	U54_Project 3 only docs.pdf	0.01	3/6/2020 12:51 PM	Rebecca Scholtes	Funding Proposal	Not Applicable
View	CSTP Parking Map	CSTP Parking Map .docx	0.01	3/6/2020 12:28 PM	Rebecca Scholtes	Other	Yes
View	Criticare HR/BP Manual	Criticare_Vitalcare_506N3_-_Service_manual.pdf	0.01	3/6/2020 12:28 PM	Rebecca Scholtes	Other	Not Applicable
View	Expired Air CO Manual	CO Monitor Manual.pdf	0.01	3/6/2020 12:27 PM	Rebecca Scholtes	Other	Not Applicable

Pertinent Results and Incidental Findings

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

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

   During screening we assess if female participants are pregnant.

   During screening we ask questions about underage tobacco/alcohol use, 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 research personnel should take to inform the PI of 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 underage tobacco or alcohol use or marijuana/cannabis use, although this is an illegal activity, the research 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"

HM20018290 - Caroline Cobb Amey
Effects of E-Cigarette Nicotine Delivery on Abuse Liability in Smokers (Project 3 Flux Study)

Risk Benefit Complete

[redacted] Progress:
[redacted]L SETUP
[redacted]GROUND, RATIONALE & GOALS
[redacted]ARCH PLAN
[redacted]ENT PLAN
[redacted]S, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Populations with Special Considerations

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

a) Specifically included in this study or

b) Discernable in the research data/specimens.

(Selections will branch)

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

HM20018290 - Caroline Cobb Amey
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Populations with Special Considerations Section Complete

[redacted] Progress:
[redacted]L SETUP
[redacted]GROUND, RATIONALE & GOALS
[redacted]ARCH PLAN
[redacted]ENT PLAN
[redacted], PRIVACY & CONFIDENTIALITY
[redacted]ULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Study Funding

1. * Have you applied for funding:

- (●) **Yes**
- ( ) No

2. Is this study already funded:

- (●) **Yes**
- ( ) No

3. * Select all funding sources for this study (pending or awarded):

- [ ] Industry
- [x] **Direct Federal**
- [ ] Indirect Federal
- [ ] State/Local Government
- [ ] Non-Profit - Sponsored Project
- [ ] Non-Profit - Gift
- [ ] Internal Grant
- [ ] Investigator/Departmental Funds
- [ ] None
- [ ] Other

4. * In addition to providing funding support, what is the funding source's role in this study? Select all that apply:

- [x] **Solely providing funding support**
- [ ] Providing resources (e.g. study drug, device)
- [ ] Providing guidance to the researcher but does NOT make decisions about study design
- [ ] Study design/Creation of the study protocol
- [ ] Collaborator in the research (helps design and/or conduct the study) [list the funder as a site on the Types of Sites page]
- [ ] Data or sample analysis regardless of identifiability

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

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

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

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

- ( ) Yes
- (●) **No**

Types of Sites

VCU Site Information

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

Non-VCU Site Information

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

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

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

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

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

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

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Informed Consent	P3 FLUX_Informed Consent_12.07.2022_CLEAN.pdf	0.29	2/27/2023 12:23 AM	Rebecca Scholtes	Consent/Assent/Information Sheet	Yes
View	Consent - Tool	P3FLUX_Consent_Presentation_12.07.2022_CLEAN.pptx	0.13	12/7/2022 2:37 PM	Rebecca Scholtes	Other	Yes
View	Text, Email, Call Scripts	Phone_e-mail_text scripts_CLEAN__12.07.2022.docx	0.19	12/7/2022 2:35 PM	Rebecca Scholtes	Other	Yes
View	COVID-19 Questions	NO LONGER USING_COVID_Questions_P3_12.07.2022.docx	0.06	12/7/2022 2:33 PM	Rebecca Scholtes	Other	No
View	Information about Blood	BP results P3 flux 8.22.2022.docx	0.01	8/22/2022 11:43 AM	Rabia Imran	Other	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Pressure						
View	P3 Flux Advertisement for CSTP Website	P3 FLUX Description for CSTP Website_CLEAN_03.30.2022.docx	0.05	4/13/2022 10:36 AM	Rebecca Scholtes	Recruitment/Advertising	Yes
View	Referral Program Card Template	P3_Referral program card_1.13.2022.docx	0.01	1/14/2022 11:49 AM	Caroline Cobb Amey	Recruitment/Advertising	Yes
View	Baseline Self Report Physio Measures	P3- FLUX_Baseline forms All_5.21.2021_CLEAN.docx	0.14	5/24/2021 2:01 PM	Rebecca Scholtes	Research Measure	Yes
View	Follow-up Survey	P3-FLUX-Follow-up_05.21.2021_CLEAN.docx	0.11	5/24/2021 1:59 PM	Rebecca Scholtes	Research Measure	Yes
View	CP-DPT & DPT - Tool	DPT_CDPT presentation_04.26.2021_CC.pptx	0.03	4/26/2021 4:36 PM	Rebecca Scholtes	Other	Yes
View	DPT/CP-DPT - Tool VIDEO	DPT_CDPT presentation_04.26.2021_CC.mp4	0.02	4/26/2021 4:35 PM	Rebecca Scholtes	Other	Yes
View	Drug Purchase Tasks (DPT)	P3-FLUX-Drug Purchase Tasks_04.26.2021_CLEAN.docx	0.03	4/26/2021 12:23 PM	Rebecca Scholtes	Research Measure	Yes
View	Puff Limiting Software Details	P3-Flux Puff Limiting Software.docx	0.01	3/19/2021 3:54 PM	Caroline Cobb Amey	Other	Not Applicable
View	Consent - Tool VIDEO	No_Longer_Using_This_Tool.docx	0.03	1/26/2021 11:37 AM	Rebecca Scholtes	Other	No
View	Facebook Advertisements	facebook ads_01.25.2021.docx	0.01	1/26/2021 10:16 AM	Rebecca Scholtes	Recruitment/Advertising	Yes
View	Combined PRT/CP-PRT - Tool	1.19_21_combinedPRT_instructions..pptx	0.02	1/25/2021 9:20 PM	Rebecca Scholtes	Other	Yes
View	Progressive Ratio Task (PRT)	PRT_FLUX_V3_1.22.21.pdf	0.03	1/25/2021 9:19 PM	Rebecca Scholtes	Research Measure	Yes
View	Subjective Measures	P3-FLUX-Session Subjective Measures_01.25.2021_CLEAN.doc	0.05	1/25/2021 4:45 PM	Rebecca Scholtes	Research Measure	Yes
View	CP-PRT - Tool	No_Longer_Using_This_Tool.docx	0.02	9/30/2020 1:48 PM	Rebecca Scholtes	Other	No
View	PRT - Tool	No_Longer_Using_This_Tool.docx	0.02	9/30/2020 1:47 PM	Rebecca Scholtes	Other	No
View	Subjective Measures - Tool VIDEO	Subjective Measures presentation_09.02.2020.mp4	0.01	9/9/2020 10:54 PM	Rebecca Scholtes	Other	Yes
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View	U54 Project 3 Grant Docs	U54_Project 3 only docs.pdf	0.01	3/6/2020 12:51 PM	Rebecca Scholtes	Funding Proposal	Not Applicable
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View	Criticare HR/BP Manual	Criticare_Vitalcare_506N3_-_Service_manual.pdf	0.01	3/6/2020 12:28 PM	Rebecca Scholtes	Other	Not Applicable
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HM20018290 - Caroline Cobb Amey
Effects of E-Cigarette Nicotine Delivery on Abuse Liability in Smokers (Project 3 Flux Study)

Personnel

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

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

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

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

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

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

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
				Data Entry Data Coding Participant Recruitment Data Collection - Interviews/Surveys				
View	Madison Combs	Research Assistant		Data Analysis Data Collection - Direct Observation Participant Consent Data Collection - Lab Data Management Data Entry Data Coding Participant Recruitment Data Collection - Interviews/Surveys		Experience - Research Education and/or Professional Preparation		no
View	Rose Bono	Research Assistant		Data Analysis Data Management Data Coding		Experience - Research Education and/or Professional Preparation		no
View	Akansha Anbil	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 Education and/or Professional Preparation		no

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

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

There are no items to display

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

Communication with between laboratory staff and the Co-PIs/Medical Monitor occurs as soon as possible during

and/or after any adverse event occurs. The Co-PIs and Medical Monitor are available by mobile phone, office phone, and email. These numbers are posted centrally in the laboratory.

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

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Informed Consent	P3 FLUX_Informed Consent_12.07.2022_CLEAN.pdf	0.29	2/27/2023 12:23 AM	Rebecca Scholtes	Consent/Assent/Information Sheet	Yes
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View	Information about Blood Pressure	BP results P3 flux 8.22.2022.docx	0.01	8/22/2022 11:43 AM	Rabia Imran	Other	Yes
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View	Baseline Self Report Physio Measures	P3- FLUX_Baseline forms All_5.21.2021_CLEAN.docx	0.14	5/24/2021 2:01 PM	Rebecca Scholtes	Research Measure	Yes
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View	PRT - Tool	No_Longer_Using_This_Tool.docx	0.02	9/30/2020 1:47 PM	Rebecca Scholtes	Other	No
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Conflict of Interest

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

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

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

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

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

4. **Describe any 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.
   Dr. Eissenberg is named on a patent application for a device that measures the puffing behavior or electronic cigarette users.

Other VCU Requirements

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

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

1. Cost Coverage Analysis

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

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

2. ClinicalTrials.gov Program & OnCore

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

1. * **Is this a Clinical Trial?**
   - ● **Yes** ○ No
2. * **ThePI acknowledges awareness of the following requirements for posting clinical trial consent forms:**

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

   - ● **Yes** ○ No

3. Community Engagement

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

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

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

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

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

5. Research Data Privacy Requirements

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

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

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

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

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

   See help text for information on accessing the VCU Data Classification Tool, and for information on creating a data security management plan at https://dms.vcu.edu**.**

   - (●) **Category 1: all data that require breach notifications in the event of improper release, including personally identifiable information covered by HIPAA and Commonwealth of Virginia regulations.**
   - ( ) Category 2: all proprietary data that if improperly released has the potential to cause harm to the institution, its mission or its reputation that do not require breach notifications.

2. * **I confirm use of the VCU Data Classification Tool at** https://go.vcu.edu/dataclassification **in determining the data classification category selected in Question 1:**

   - (●) **Yes**
   - ( ) No

3. * **The PI is aware that if the study's data is classified as Category 1, a Data Management Plan must be submitted to and approved by VCU Information Security prior to IRB approval. See** https://ts.vcu.edu/askit/essential-computing/information-security/data-management-system/

   (●) **Yes** ( ) No

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

   I also confirm that if the study involves use of external technology and VCUHS HIPAA data, I must also seek security review from the VCUHS Data Governance group (contact Mary Harmon at mary.harmon@vcuhealth.org):

   - (●) **Yes**
   - ( ) No
   - ( ) N/A - not using external technology

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

1. * **Does this study involve any of the following?**
   - Research involving patients with cancer, their families or their health care providers
   - Research involving cancer screening, diagnosis or prevention
   - Secondary data collected from cancer patients or their medical records
   - Cancer-related surveys (e.g., attitudes about risk, prevention and treatment) of the general population

   - ( ) Yes
   - (●) **No**

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

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

   - VCU Health System patients

   - VCU Health System facilities

   - VCU Health System data
   - ( ) Yes
   - (●) **No**

9. VCU Health Department of Patient Centered Services

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

○ No

● **Not Applicable**

10. VCU Faculty-Held IND or IDE

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

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

11. VCU Health System locations

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

○ Yes

● **No**

12. VCUHS Department of Pathology

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

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

● **Yes**

○ No

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

○ Yes

○ No

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

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

○ Yes

○ No

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

13. VCU Institutional Biosafety Committee (IBC)

To contact the Biosafety Office see their website at: https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/

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

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

- Expression or administration of biological toxins.

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

- Introduction or expression of rDNA or synthetic nucleic acids

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

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

○ Yes ● **No**

14. VCU Radiation Safety Committee (RSC)

To contact the Radiation Safety Section see their website at: https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/

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

   ◯ Yes

   ● **No**

15. VCU Scientific Review Committee (SRC)

For guidance, see https://cctr.vcu.edu/support/consultation/scientific-review-committee/

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

   ◯ Yes

   ● **No**

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

16. Upload any documents requested in the questions above:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Informed Consent	P3 FLUX_Informed Consent_12.07.2022_CLEAN.pdf	0.29	2/27/2023 12:23 AM	Rebecca Scholtes	Consent/Assent/Information Sheet	Yes
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HM20018290 - Caroline Cobb Amey
Effects of E-Cigarette Nicotine Delivery on Abuse Liability in Smokers (Project 3 Flux Study)

Institutional Requirements Complete

[redacted] Progress:
[redacted]L SETUP
[redacted]GROUND, RATIONALE & GOALS
[redacted]ARCH PLAN
[redacted]ENT PLAN
[redacted]S, PRIVACY & CONFIDENTIALITY
[redacted]LATIONS WITH SPECIAL CONSIDERATIONS
[redacted]ITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

HM20018290 - Caroline Cobb Amey
Effects of E-Cigarette Nicotine Delivery on Abuse Liability in Smokers (Project 3 Flux Study)

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.

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View	CSTP Registry Consent Document	CSTP_Consent and screening_registry questions updated 4.29.19 CHANGES ACCEPTED.pdf	0.01	4/2/2020 3:36 PM	Rebecca Scholtes	Consent/Assent/Information Sheet	Not Applicable
View	BHRL Registry Consent Document	HM20007677 Consent Form_06.21.2019_CLEAN.pdf	0.01	4/2/2020 3:33 PM	Rebecca Scholtes	Consent/Assent/Information Sheet	Not Applicable
View	Presession Symptom Questions	P3-FLUX-Presession symptom Checklist-01.09.2019.docx	0.01	4/2/2020 12:47 AM	Rebecca Scholtes	Research Measure	Yes
View	Barnes Biosketch	P3 Barnes biosketch 06.22.17.FINAL.docx	0.01	4/1/2020 11:23 PM	Rebecca Scholtes	CV/Biosketch	Not Applicable
View	Lipato Biosketch	Lipato Biosketch_10.5.16.docx	0.01	4/1/2020 11:22 PM	Rebecca Scholtes	CV/Biosketch	Yes
View	Caroline Cobb (Amey) CV	Curriculum Vitae_Cobb_December 2019.docx	0.01	3/9/2020 11:16 AM	Caroline Cobb Amey	CV/Biosketch	Yes
View	Baseline Discounting Task - MDT	P3_FLUX_Discounting Task_11.7.2018.pdf	0.01	3/6/2020 1:26 PM	Rebecca Scholtes	Research Measure	Yes
View	Baseline Risk Taking Task - BART	P3_FLUX_BART_screenshot.11.8.2018.pdf	0.01	3/6/2020 1:26 PM	Rebecca Scholtes	Research Measure	Yes
View	U54 Project 3 Grant Docs	U54_Project 3 only docs.pdf	0.01	3/6/2020 12:51 PM	Rebecca Scholtes	Funding Proposal	Not Applicable
View	CSTP Parking Map	CSTP Parking Map .docx	0.01	3/6/2020 12:28 PM	Rebecca Scholtes	Other	Yes
View	Criticare HR/BP Manual	Criticare_Vitalcare_506N3_-_Service_manual.pdf	0.01	3/6/2020 12:28 PM	Rebecca Scholtes	Other	Not Applicable
View	Expired Air CO Manual	CO Monitor Manual.pdf	0.01	3/6/2020 12:27 PM	Rebecca Scholtes	Other	Not Applicable

HM20018290 - Caroline Cobb Amey
Effects of E-Cigarette Nicotine Delivery on Abuse Liability in Smokers (Project 3 Flux Study)

Documents Complete

[redacted] Progress:
[redacted]L SETUP
[redacted]GROUND, RATIONALE & GOALS
[redacted]ARCH PLAN
[redacted]ENT PLAN
[redacted]S, PRIVACY & CONFIDENTIALITY
[redacted]LATIONS WITH SPECIAL CONSIDERATIONS
[redacted]TUTIONAL REQUIREMENTS
[redacted]UMENTS

End of Application

Click Continue below to exit and submit this project

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

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

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

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

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

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

☑	**Principal Investigator**
☑	**Co/Sub-Investigator**
☐	Medical or Psychological Responsible Investigator
☐	Lead Student/Trainee Investigator (leading their own project)

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

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

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

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

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

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
   The consent form emphasizes the voluntary nature of the research study and staff are well-trained to ensure individuals understand their rights as a research participant. A copy of the consent form is given to all potential participants to take with them. They are informed that that they can go home and/or discuss their participation with others prior to signing the form.

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

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

Personnel

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

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

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

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

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

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

4. * **Study related responsibilities:**

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

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

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

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

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

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Andrew Barnes

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

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

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

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

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

4. * **Study related responsibilities:**

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

- [ ] Intervention Services
- [x] **Data Entry**
- [x] **Data Coding**
- [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:**
   Alison Breland

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

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

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

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

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

4. * **Study related responsibilities:**

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

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

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

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

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

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Thomas Eissenberg

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

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

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

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

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

4. * **Study related responsibilities:**

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

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

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

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

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

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Thokozeni Lipato

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

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

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

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

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

4. * **Study related responsibilities:**

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

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

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

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

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

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Nicoleta Gaitan

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

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

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

   ○ Yes
   ● **No**

3. * **Roles:**

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

4. * **Study related responsibilities:**

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

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

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

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

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

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

8. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Rabia Imran

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

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

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

   ○ Yes
   ● **No**

3. * **Roles:**

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

4. * **Study related responsibilities:**

- [ ] Study Design
- [x] **Data Collection - Lab**
- [ ] Data Collection - Clinical
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- [x] **Data Analysis**
- [x] **Project Coordination**
- [ ] Participant Identification
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

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

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

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

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Augustus White

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

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

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

   ○ Yes
   ● **No**

3. * **Roles:**

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

4. * **Study related responsibilities:**

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

Personnel

1. * **Name:**
   Madison Combs

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

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

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

   ○ Yes
   ● **No**

3. * **Roles:**

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

4. * **Study related responsibilities:**

- [ ] Study Design
- [x] **Data Collection - Lab**
- [ ] Data Collection - Clinical
- [x] **Data Collection - Interviews/Surveys**
- [x] **Data Collection - Direct Observation**
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- [x] **Data Analysis**
- [ ] Project Coordination
- [ ] Participant Identification
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

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

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

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

7. **Additional or Emergency Phone:**

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
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other

4. * **Study related responsibilities:**

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

- [ ] Intervention Services
- [ ] Data Entry
- [x] **Data Coding**
- [x] **Data Management**
- [x] **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
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Akansha Anbil

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

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

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

   ○ Yes
   ● **No**

3. * **Roles:**

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

4. * **Study related responsibilities:**

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

- [ ] Intervention Services
- [x] **Data Entry**
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [ ] 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
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Add Document

1. * **Document Name:**
   Informed Consent
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   P3 FLUX_Informed Consent_12.07.2022_CLEAN.pdf(0.29)

Add Document

1. * **Document Name:**
   Consent - Tool
2. * **Type:**
   Other
3. * **File:**
   P3FLUX_Consent_Presentation_12.07.2022_CLEAN.pptx(0.13)

Add Document

1. * **Document Name:**
   Text, Email, Call Scripts
2. * **Type:**
   Other
3. * **File:**
   Phone_e-mail_text scripts_CLEAN__12.07.2022.docx(0.19)

Add Document

1. * **Document Name:**
   COVID-19 Questions
2. * **Type:**
   Other
3. * **File:**
   NO LONGER USING_COVID_Questions_P3_12.07.2022.docx(0.06)

Add Document

1. * **Document Name:**
   Information about Blood Pressure
2. * **Type:**
   Other
3. * **File:**
   BP results P3 flux 8.22.2022.docx(0.01)

Add Document

1. * **Document Name:**
   P3 Flux Advertisement for CSTP Website
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   P3 FLUX Description for CSTP Website_CLEAN_03.30.2022.docx(0.05)

Add Document

1. * **Document Name:**
   Referral Program Card Template
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   P3_Referral program card_1.13.2022.docx(0.01)

Add Document

1. * **Document Name:**
   Baseline Self Report Physio Measures
2. * **Type:**
   Research Measure
3. * **File:**
   P3- FLUX_Baseline forms All_5.21.2021_CLEAN.docx(0.14)

Add Document

1. * **Document Name:**
   Follow-up Survey
2. * **Type:**
   Research Measure
3. * **File:**
   P3-FLUX-Follow-up_05.21.2021_CLEAN.docx(0.11)

Add Document

1. * **Document Name:**
   CP-DPT & DPT - Tool
2. * **Type:**
   Other
3. * **File:**
   DPT_CDPT presentation_04.26.2021_CC.pptx(0.03)

Add Document

1. * **Document Name:**
   DPT/CP-DPT - Tool VIDEO
2. * **Type:**
   Other
3. * **File:**
   DPT_CDPT presentation_04.26.2021_CC.mp4(0.02)

Add Document

1. * **Document Name:**
   Drug Purchase Tasks (DPT)
2. * **Type:**
   Research Measure
3. * **File:**
   P3-FLUX-Drug Purchase Tasks_04.26.2021_CLEAN.docx(0.03)

Add Document

1. * **Document Name:**
   Puff Limiting Software Details

2. * **Type:**
   Other

3. * **File:**
   P3-Flux Puff Limiting Software.docx(0.01)

Add Document

1. * **Document Name:**
   Consent - Tool VIDEO
2. * **Type:**
   Other
3. * **File:**
   No_Longer_Using_This_Tool.docx(0.03)

Add Document

1. * **Document Name:**
   Facebook Advertisements
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   facebook ads_01.25.2021.docx(0.01)

Add Document

1. * **Document Name:**
   Combined PRT/CP-PRT - Tool
2. * **Type:**
   Other
3. * **File:**
   1.19_21_combinedPRT_instructions..pptx(0.02)

Add Document

1. * **Document Name:**
   Progressive Ratio Task (PRT)
2. * **Type:**
   Research Measure
3. * **File:**
   PRT_FLUX_V3_1.22.21.pdf(0.03)

Add Document

1. * **Document Name:**
   Subjective Measures
2. * **Type:**
   Research Measure
3. * **File:**
   P3-FLUX-Session Subjective Measures_01.25.2021_CLEAN.doc(0.05)

Add Document

1. * **Document Name:**
   CP-PRT - Tool
2. * **Type:**
   Other
3. * **File:**
   No_Longer_Using_This_Tool.docx(0.02)

Add Document

1. * **Document Name:**
   PRT - Tool
2. * **Type:**
   Other
3. * **File:**
   No_Longer_Using_This_Tool.docx(0.02)

Add Document

1. * **Document Name:**
   Subjective Measures - Tool VIDEO
2. * **Type:**
   Other
3. * **File:**
   Subjective Measures presentation_09.02.2020.mp4(0.01)

Add Document

1. * **Document Name:**
   Subjective Measures -Tool
2. * **Type:**
   Other
3. * **File:**
   Subjective Measures presentation_09.02.2020.pptx(0.02)

Add Document

1. * **Document Name:**
   Cross Product Progressive Ratio Task (CP-PRT)
2. * **Type:**
   Research Measure
3. * **File:**
   CP_PRT_Flux_V2_08.04.2020.pdf(0.02)

Add Document

1. * **Document Name:**
   Flux Advertisements
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   FLUX_Combined Ads_07.20.2020_V3_CLEAN.pdf(0.05)

Add Document

1. * **Document Name:**
   CSTP Registry Consent Document
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   CSTP_Consent and screening_registry questions updated 4.29.19 CHANGES ACCEPTED.pdf(0.01)

Add Document

1. * **Document Name:**
   BHRL Registry Consent Document
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   HM20007677 Consent Form_06.21.2019_CLEAN.pdf(0.01)

Add Document

1. * **Document Name:**
   Presession Symptom Questions
2. * **Type:**
   Research Measure
3. * **File:**
   P3-FLUX-Presession symptom Checklist-01.09.2019.docx(0.01)

Add Document

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

Add Document

1. * **Document Name:**
   Lipato Biosketch
2. * **Type:**
   CV/Biosketch
3. * **File:**
   Lipato Biosketch_10.5.16.docx(0.01)

Add Document

1. * **Document Name:**
   Caroline Cobb (Amey) CV
2. * **Type:**
   CV/Biosketch
3. * **File:**
   Curriculum Vitae_Cobb_December 2019.docx(0.01)

Add Document

1. * **Document Name:**
   Baseline Discounting Task - MDT
2. * **Type:**
   Research Measure
3. * **File:**
   P3_FLUX_Discounting Task_11.7.2018.pdf(0.01)

Add Document

1. * **Document Name:**
   Baseline Risk Taking Task - BART
2. * **Type:**
   Research Measure
3. * **File:**
   P3_FLUX_BART_screenshot.11.8.2018.pdf(0.01)

Add Document

1. * **Document Name:**
   U54 Project 3 Grant Docs
2. * **Type:**
   Funding Proposal
3. * **File:**
   U54_Project 3 only docs.pdf(0.01)

Add Document

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

Add Document

1. * **Document Name:**
   Criticare HR/BP Manual
2. * **Type:**
   Other
3. * **File:**
   Criticare_Vitalcare_506N3_-_Service_manual.pdf(0.01)

Add Document

1. * **Document Name:**
   Expired Air CO Manual
2. * **Type:**
   Other
3. * **File:**
   CO Monitor Manual.pdf(0.01)