Document Coversheet

Study Title: Effects of filter ventilation and ventilation information on product use behaviors in cigarette smokers (COMET 2 3.1)

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PROTOCOL TITLE:

Effects of Filter Ventilation and Ventilation Information on Product Use Behaviors in Cigarette Smokers (COMET 2 3.1)

PROTOCOL NUMBER:

I 757820

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Confidentiality Statement

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1 OBJECTIVES

1.1 Purpose, Specific Aims, or Objectives

In this project, we will assess whether messaging about ventilation from cigarette filters lowers cigarette product appeal among smokers. This study, part of a series (I 50217, I 59617) will help determine whether a regulatory requirement to reduce ventilation will lower demand for cigarettes without unintended consequences This project will assess the effect of variation in pack messaging about filter ventilation on consumers' rating of product appeal, perceptions of health risks, and changes in cigarette consumption in a 2-week field study. Our *premise* is that messaging about risks of filter ventilation will reduce the appeal of cigarette smoking and increase the likelihood that smokers would either quit smoking or switch to an alternative product (e.g., electronic cigarettes). This project is well-integrated with the other studies in this P01, using the same standardized research cigarettes with defined ventilation characteristics and design parameters, as well as relying on common biobehavioral measures.

The aim of the proposed study is to assess how adding messaging to cigarette packages about filter vents and filters influences respondents awareness of filter ventilation, beliefs about the function of filter vents and filters, smoking behavior, ratings of cigarette satisfaction, smoking topography, exposure to nicotine and carbon monoxide, perceptions about the risk of smoking, and intention to stop smoking.[6] The protocol will consist of a randomized experiment via two-week field study.

1.2 Hypothesis

We hypothesize that exposing smokers to messages about filter vents and filters will increase awareness and knowledge of the impact of filter ventilation on cigarette smoking behavior and increase intention to stop smoking. Exposure to messages on packs will also lower ratings of cigarette satisfaction but have no significant impact on smoking behavior, topography, and exposure to nicotine and carbon monoxide.

2 BACKGROUND

2.1 Prior Experience and Gaps in Current Knowledge

The physical design features of cigarette products directly impact their appeal by influencing both cognitive and sensory perceptions. The introduction of a now common design feature, filter ventilation, has led to greater public harm than benefit because of the potential for greater toxicity while enhancing product appeal among smokers. Ventilated cigarettes dilute smoke, which promotes perceptions of "smoothness" and therefore lower health risk, contributing to the overall appeal of these products. Tobacco product appeal is driven by factors including abuse liability (i.e. the potential for tobacco products to initiate and maintain nicotine dependence), subjective responses (e.g., liking, satisfaction, taste perceptions), and perceptions of cigarette pack messaging and other marketing strategies (including normative beliefs, risk perceptions, perceived benefits, outcome expectancies, use intentions, & product purchase). These perceptions and beliefs are further shaped by cigarette manufacturers' use of descriptive terms and colors on packaging designs and advertising.

In this project, we will assess whether messaging about ventilation from cigarette filters lowers cigarette product appeal among smokers. This project is *significant* because it will generate

tobacco product regulatory science to support future policy approaches to filter ventilation that may reduce demand for cigarettes and the population harm associated with their use.

This project is *innovative* because it will generate novel science that informs our understanding on interactions between product physical design and messaging influence smokers' perceptions of the product appeal and health risk.

2.2 Relevant Preliminary Data

The PI (O'Connor) and the investigative team have extensive experience in examining biobehavioral responses to cigarette design. Pilot research relevant to the current proposal (Rees, unpublished) assessed responses to "light" cigarettes and packaging. Participants (N=90) were current smokers whose brand of choice was Marlboro "Lights"/Gold. Using a factorial design, participants were randomized to receive a Marlboro "Lights" cigarette presented in one of three pack conditions 1) text descriptors present; 2) text descriptor removed; and 3) plain (brown) pack. Participants smoked two cigarettes, in counterbalanced order: 1) blocked and 2) unblocked. A significant interaction was observed between pack design and ventilation on measures of smoking *Effect* (p=0.007), with the ventilated cigarette producing greater perceived effect as pack descriptors were removed, and *Throat Impact* (a cue for nicotine delivery) (p=0.039). Pack design and ventilation also interacted to influence sensory perceptions of irritation, and taste (p's< 0.017), with higher ratings seen on plain packs with blocked ventilation.

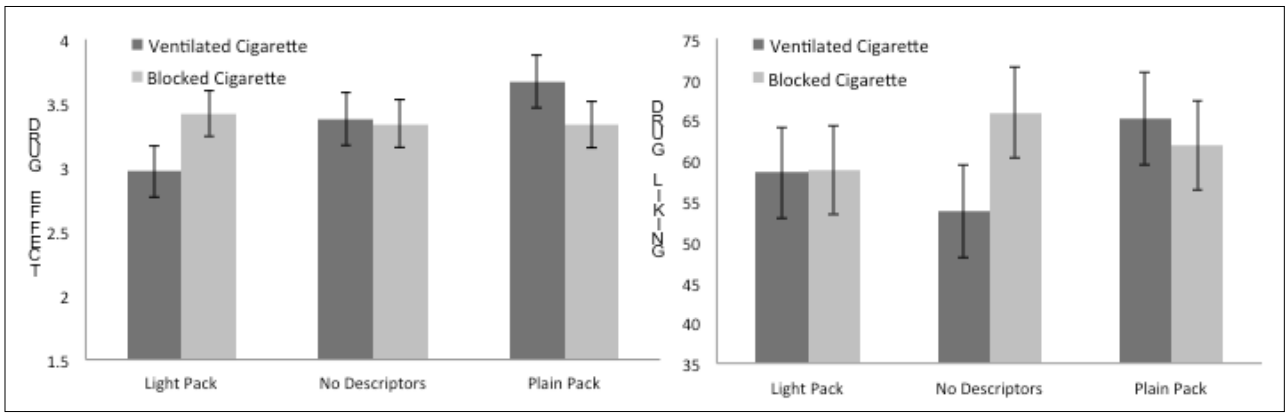

Figure 1. Interaction of filter ventilation and pack descriptor on drug effect and liking measures.

Figure 1 shows that *variation in filter ventilation interacts with pack descriptors to influence drug effect and liking.* Web-based survey work (conducted in August-September 2016) funded under the prior COMET project (under protocol I 218912) included items on awareness of filter ventilation among smokers,[113] and an administration of the mCEQ.[96] Among the 1986 current smokers in the sample, 44.7% were aware of filter vents in cigarettes, while 45.7% were unaware, and 9.7% replied 'don't know.' Smokers aged 18-34 were more likely than those aged 35+ to be aware of vents (49.9% vs. 32.4%, <.001). Men were substantially more likely than women to be aware of vents (60.1% vs. 30.0%, p<.0001). Most smokers (among those aware; n=1079) believed that covering the vents would make the cigarette taste stronger (58.6%), though 15% reported 'don't know.' Those aged 18-34 were slightly more likely to believe covering vents would make cigarettes stronger (59.9% vs. 52.1%), though older smokers were more likely to say 'don't know' (10.9% vs. 27.4%). All in all, these data suggest continued lack of awareness of filter ventilation among smokers. Overall, 30.4% of smokers believed their cigarette was lighter in taste than other

cigarettes on the market, and 29.7% believe their cigarettes were smoother on the throat. Nearly half (46.9%) reported that they enjoyed the taste of their cigarettes 'a lot.'

2.3 Scientific or Scholarly Background for, Rationale for, and Significance of the Research Based on the Existing Literature and How Will It Add to Existing Knowledge

An important design feature that separates cigarette brand variants is the degree of filter ventilation, achieved by the placement of holes in cigarette filters.[1-3] Filter ventilation has contributed to population harm by attracting new users and diverting existing smokers from quitting.[4,11-16] Filter ventilation is deceptive in this regard because most smokers are unaware of it,[18-21] and it promotes taking larger puffs by reducing resistance to draw.[4,5,22] Smokers fingers and lips may also block vents during smoking, reducing or even eliminating the smoke dilution effect.[4,23-29] Smokers of 'light' and 'ultralight' brands tend to take in similar levels of nicotine compared to 'regular' cigarette smokers, while often being exposed to higher concentrations of tobacco toxicants that reach deeper parts of the lung [22,30-41] and likely contributing to a higher risk for lung adenocarcinomas. Unfortunately, many smokers continue to believe that 'low tar' cigarettes are less hazardous to their health.[18,19,42-49] For all these reasons, scientists have called for restrictions on filter ventilation as a fundamentally harmful feature, which can be easily removed by cigarette manufacturers.

In order for the FDA to exert regulatory authority in this area, evidence is needed to demonstrate that regulations will benefit population health.[50] The effects of banning ventilated filters could have positive consequences. The unvented products may be rendered harsher to smoke and less appealing, which could decrease use and exposures and increase intentions to quit or substitution of less hazardous alternatives. On the other hand, removal could potentially lead to increased or similar levels of smoking behaviors and toxicant exposures among consumers because they adapt to the harsher smoke or because of higher reinforcing doses of nicotine.

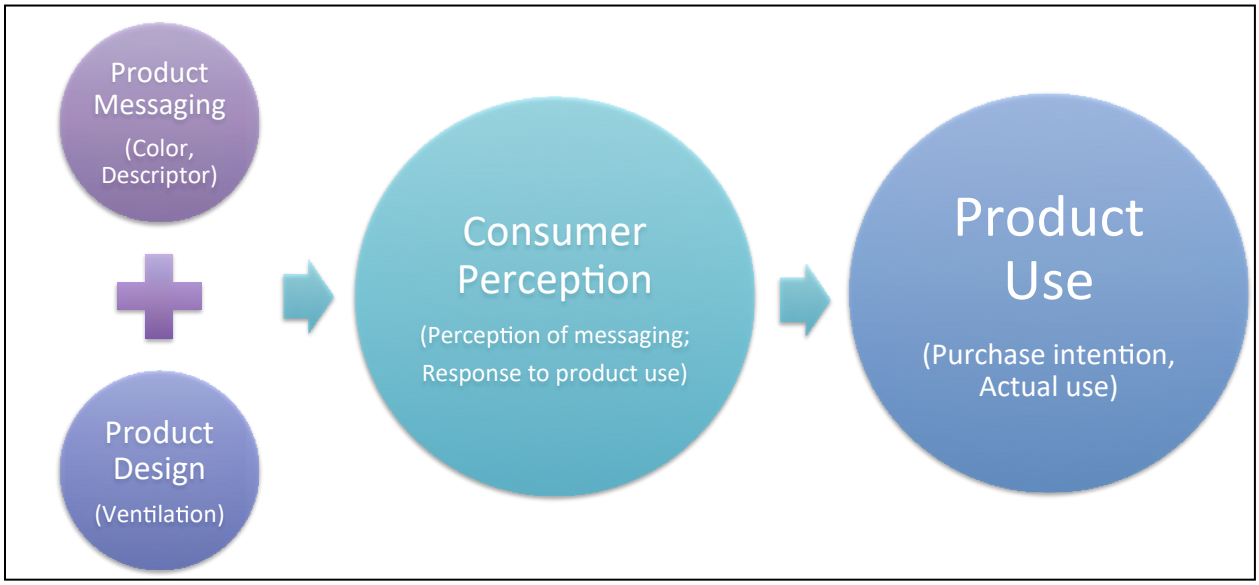

Figure 2. Conceptual Framework

Product appeal and risk perception. Two inter-related domains drive consumer trial and adoption of tobacco products [54-67], as illustrated in Figure 2. These include: i) *perceptions of product*

messaging, often communicated via the product packaging; and ii) *responses to product use,* which include both sensory and other subjective response measures. Taken together, these consumer responses reflect the combined effects of product design and branding, and the subsequent outcome of product use behavior.

Sensory factors in smoking. There is substantial evidence that sensory effects of smoking, such as harshness, smoothness, and taste of smoke, are important drivers of continued use. Initial work showed that sensory blockade reduced urge to smoke.[87,88] Rose and colleagues examined various approaches to disassociate the nicotine and sensory components of smoking reward as approaches to cessation.[89-95] Measurement approaches were developed to examine the upper airway sensory experience and factors associated with reward,[92,93,95] which would later be refined into a modified Cigarette Evaluation Questionnaire.[96] The release of internal tobacco industry research revealed the extent to which sensory factors were studied as important components of cigarette design.[55,68,97,98] Continued misperceptions of cigarettes with misleading descriptors (e.g., "light", "ultralight", "mild") are likely due to the sensory characteristics such as strength and harshness/ irritation [4,9] and filter ventilation level is related to perceptions of the relative harshness and strength of cigarettes.[40,41] Expectancies of positive sensory effects of smoking (e.g., look, feel, and taste) are predictive of smoking behavior and willingness to try different cigarettes.[99-105] This suggests that misperceptions about safety may persist as long as there is a perceptible sensory difference between products. Despite the critical regulatory science need, there are few published methods for testing tobacco products,[57,106-108] particularly as applied to a systematic evaluation of a potential product standard.

Summary & Scientific Premise. Cigarette product design directly impacts product appeal via cognitive and sensory perceptions. Ventilated cigarettes dilute smoke, which is perceived as "smoother" and thus having lower health risks, contributing to the overall appeal of these products. These perceptions and beliefs are shaped by descriptive terms and colors on used in cigarette packaging and advertising. The FDA, through the Family Smoking Prevention and Tobacco Control Act (FSPTCA),[50] has regulatory authority over tobacco products. This places cigarettes and other tobacco products under a public health regulatory framework.[109-111] Section 907 of the Act relates to the agency's ability to issue and enforce product standards. While there are substantial studies about the impact of filter ventilation on smokers' perceptions, to date there are none about the impact of removing filter ventilation. Our ***premise*** is that messaging about filter ventilation will reduce the appeal of cigarette smoking and increase the likelihood that smokers would either quit smoking or move to alternative nicotine delivery systems (ANDS), e.g., e-cigarettes or nicotine replacement therapy.

3 STUDY ENDPOINTS

- Primary 1: Subjective questionnaires of product evaluation (Duke Sensory Scale, Product Evaluation Scale, Drug Effects, Hedonic Attribute), withdrawal (MNWS, QSU-B, PANAS), and readiness to quit (contemplation ladder).
- Primary 2: Number of cigarettes smoked per week during the field period.
- Secondary: Awareness and beliefs about filter ventilation and perceptions of messaging.
- Secondary: Exhaled CO is defined as level of CO measured in exhaled breath after a 15 s breathhold. This is typically 10ppm or above in daily smokers and <3 ppm in nonsmokers.
- Secondary: Smoking topography as assessed by particulate matter retained on used filters.

4 LOCAL AND STUDY-WIDE NUMBER OF SUBJECTS

4.1 Total Number of Subjects to be Accrued Across All Sites.

We will conduct this study with current cigarette smokers (100 in Buffalo, 100 in Boston, 100 in Charleston) for a total N of 300. We hope to achieve N=240 with complete data. An equal number of males and females will be recruited for the study at each site.

Stratified recruitment scheme for Study 3.1		
	Cigarette Smoker	
Sex	*M*	*F*
Overall N	**150**	**150**
Buffalo	50	50
Boston	50	50
Charleston	50	50

4.2 Total Number of Subjects to be Accrued Locally

- Buffalo, NY will recruit an n of 100, with a target of 80 complete cases.
- Charleston, SC will recruit an n of 100, with a target of 80 complete cases.
- Boston, MA will recruit an n of 100, with a target of 80 complete cases.

5 STUDY TIMELINES

5.1 Duration of an Individual Subject's Participation in the Study

The proposed study consists of multiple videoconferencing sessions (a total of 3) throughout a 2-week field study. Following informed consent, participants will be randomly assigned to 1 of 4 message conditions and use the assigned product for 2 weeks. This 2-week field study involves participants logging their use of tobacco products, while the weekly videoconferencing sessions involve additional questionnaires and guidance about field data collection.

	Data Collection Sessions (Weekly)			Field (Daily for 14 days)
	Video 1	**Video 2**	**Video 3**	**Ecological Momentary Assessment**
Tobacco Use Behavior				
Cigarettes per Day	X	X	X	X
Other Tobacco Use	X	X	X	X
Context of Use (e.g., location)				X
Questionnaires				
Message Perceptions (response, health risk, purchase)	X All messages	X Randomly Assigned Message	X Randomly Assigned Message	
Vent Awareness	X	X	X	
Product Evaluation (Duke Sensory, Product Evaluation Scale, Drug Effects, Hedonic Attribute)	X	X	X	X Select Items
Readiness to Quit (Contemplation Ladder)	X	X	X	
Withdrawal (MNWS, QSU-B, PANAS)				X Select Items
Attention to Messaging				X
Biomarkers				
Exhaled CO				X
Topography via Filter Analysis				X

Estimated date for the investigators to complete this study

Data collection should be completed by 12/31/2022.

6 SETTING

6.1 Sites or Locations Where Research Will Be Conducted

We will conduct this laboratory study in Buffalo, Charleston, and Boston.

6.1.1 Where Research Team Will Identify and Recruit Potential Subjects

We will recruit for our laboratory study via community contacts, ad postings in local, daily, weekly, and college newspapers, websites such as Craigslist and Facebook, and local tobacco control networks (methods we have previously used to recruit successfully, cf. [71,152,153]). In addition, we plan to make arrangements with local shopping centers to allow recruitment of patrons on-site.

6.1.2 Where Research Procedures Will Be Performed

Remote visits will involve participants joining videoconferences in their own homes.

7 INCLUSION AND EXCLUSION CRITERIA

7.1 How Individuals Will Be Screened For Eligibility

We will recruit adult smokers for the study via community contacts, ad postings in local daily, weekly, and college newspapers, websites such as Craigslist and Facebook, and local tobacco control networks (methods we have previously used to recruit successfully, cf. [71,152,153]).

Screening methods may involve live telephone interviews, automated telephone screeners (via IVR), and online screening methods where the recruit will complete an eligibility screener online and receive a callback for scheduling pending eligibility.

7.2 Inclusion Criteria

1. Aged 21-69 years old.
2. Currently smoking daily, at least 5 cigarettes per day, for the past year:
    a. Primarily using factory-made filtered cigarettes.
3. Fair and above self-rated physical health (self-rated).
4. Fair and above self-rated mental health (self-rated).
5. Not planning to quit smoking in the next 30 days.
6. Able to converse, read, and write in English.
7. Access to smartphone (e.g., iPhone, Android) for Ecological Momentary Assessment (EMA) component.
8. Access to a smartphone/tablet/computer with video capabilities and internet access for remote videoconferencing (EMA check-ins).
9. AUDIT-C score <7 (i.e., no problematic alcohol consumption).
10. Cannabis use ≤5 days in the past month.
11. No other illegal drug use in the past month (allow for prescriptions).
12. Not pregnant or breastfeeding or planning to become pregnant during the study period.
13. Participant must understand the investigational nature of this study and sign an Independent Ethics Committee/Institutional Review Board approved written informed consent form prior to receiving any study related procedure.

7.3 Exclusion Criteria

1. Age < 21 or > 69.
2. Using roll-your-own cigarettes or usual brand of cigarettes is unfiltered.
3. Planning to quit smoking in the next 30 days.
4. Not able to converse, read, and write in English.
5. Adults unable to consent.
6. Minors (any persons under age 21).
7. Prisoners.
8. Poor physical health by self-report.
9. Poor mental health by self-report:

- Exclude Dx psychosis, Dx bipolar, K6 score indicating serious psychological distress.

10. AUDIT-C score ≥7 (i.e. problematic alcohol consumption).
11. Cannabis use >5 days in past month.
12. Other illegal drug use in past month.
13. Pregnant or breastfeeding by self-report.
14. No access to smartphone or videoconferencing.

7.4 Inclusion of Women and Minorities

Both men and women and members of all races and ethnic groups are eligible for this study.

7.5 Special Populations

The following populations will be excluded from study participation:

- Cognitively impaired adults/adults with impaired decision-making capacity
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant Women
- Prisoners

8 LOCAL AND STUDY-WIDE RECRUITMENT METHODS

8.1 When, Where, and How Potential Subjects Will Be Recruited

We will recruit for our laboratory study via community contacts, ad postings in local daily, weekly, and college newspapers, websites such as Craigslist and Facebook, and local tobacco control networks, and lists of prior study participants (methods we have previously used to recruit successfully, cf. [71,152,153]).

8.2 Methods That Will Be Used to Identify Potential Subjects

Screening methods may involve live telephone interviews, automated telephone screeners (via IVR), and online screening methods where the recruit will complete an eligibility screener online and receive a callback for scheduling pending eligibility.

Additionally, we plan to implement a chain referral method. This method has been successfully used in other participant-based studies. Here, all participants who complete the study will be given a "coupon book" containing 3 "coupons" (Appendix A), each with a unique code per participant. The participant may give a coupon to a friend/colleague/relative if they choose. The friend, in turn, may voluntarily call in to complete the screener, just as if they saw an ad. Should the friend successfully complete the study and return the coupon, the original participant may earn $10 per referral (up to a maximum of $30). A gift code (e.g., Amazon, Target) will be e-mailed upon the close of the entire study, guaranteeing the maximum amount of time to earn the largest monetary reward. Finally, letters (Appendix A) will be mailed to the home address of participants who have previously completed a tobacco-related studies as the one of the three study sites (i.e., Roswell Park Comprehensive Cancer Center, Medical University of South Carolina, and Harvard School of Public Health) and gave consent to be contacted in the future for other research opportunities.

8.3 Materials That Will Be Used to Recruit Subjects

Ad and chain referral materials included (Appendix A).

8.4 Amount and Timing of Any Payments to Subjects

Participants receive $50 for each videoconference session (three total). Payment will be in the form of a gift code (e.g., Amazon, Target). Participants can earn up to $10 for each day of EMA compliance (up to 14 days, totaling $140), which will be paid by check at the end of the study. Total potential compensation is $290.

9 CONSENT PROCESS

9.1 Indication of Obtaining Consent

An initial videoconferencing session will be used for informed consent. Consent will be obtained through the REDCap (Research Electronic Data Capture) system used for data collection. REDCap is a secure web-based application that supports data capture and management for research studies. The Investigator and Research Associate will design the study specific consent and upload the most recent CRS versions to the REDCap system. A secure link will be sent to each participant prior to the start time of the study. Research staff will guide the participant form, provide time to read the consent, and answer any questions. Participants and staff will be able to electronically sign, data, and submit the consent in real-time. Once the consent is submitted, it is automatically saved on RPCI protected servers. Access to this folder is restricted to authorized users. Standard protocols for data encryption (via Credant) when using laptops and USB drives will be followed.

In the event of REDCAP being inaccessible for a study visit, .pdf files or paper copes of the consent will be provided to the participants and the participants will be able to sign and return or submit a photo of the signed copy.

9.2 Where the Consent Process Will Take Place

Consent will take place via video-conference.

9.3 SOP: Informed Consent Process for Research (HRP-090)

Standard SOP and Summary of Current Guidance on Alternative Informed Consent Procedures for Research Studies Impacted by COVID-19.

For Multi-Site Study: This study will not be initiated until the protocol and informed consent document(s) have been reviewed and approved by a properly constituted Institutional Review Board (IRB) or Independent Ethics Committee (IEC). Each participant (or legal guardian) shall read, understand, and electronically sign an instrument of informed consent prior to performance of any study-specific procedure. It is the responsibility of the investigator to ensure that the participant is made aware of the investigational nature of the treatment and that informed consent is given.

The Investigator is responsible for the retention of the participant log and participant records; although personal information may be reviewed by authorized persons, that information will be treated as strictly confidential and will not be made publicly available. The investigator is also responsible for obtaining participant authorization to access medical records and other applicable

study specific information according to Health Insurance Portability and Accountability Act regulations (where applicable).

This study will be conducted in compliance with all applicable laws and regulations of the state and/or country and institution where the participant is treated. The clinical trial should be conducted in accordance with the ethical principles embodied in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, consistent with good clinical practice and the applicable regulatory requirements and according to the guidelines in this protocol, including attached appendices.

10 PROCESS TO DOCUMENT CONSENT IN WRITING

10.1 SOP: Written Documentation of Consent (HRP-091)

We will obtain documentation of consent.

10.2 If Your Research Presents No More Than Minimal Risk of Harm to Subjects and Involves No Procedures for Which Written Documentation of Consent is Normally Required Outside of the Research Context, the IRB Will Generally Waive the Requirement to Obtain Written Documentation of Consent.

N/A.

10.3 Waiver of Consent Documentation

N/A.

For Multi-Site Study: The Investigator (or IRB specified designee) is responsible for obtaining written consent from each participant in accordance with GCP guidelines using the approved informed consent form, before any study specific procedures (including screening procedures) are performed. The informed consent form acknowledges all information that must be given to the participant according to applicable GCP guidelines, including the purpose and nature of the study, the expected efficacy and possible side effects of the treatment(s), and specifying that refusal to participate will not influence further options for therapy. Any additional information that is applicable to the study must also be included. Additional national or institutionally mandated requirements for informed consent must also be adhered to. The participant should also be made aware that by signing the consent form, processing of sensitive clinical trial data and transfer to other countries for further processing is allowed.

The investigator or designee shall provide a copy of the signed consent form to the participant and the signed original shall be maintained in the investigator file. A copy of the signed consent form must be filed in the participant file. At any stage, the participant may withdraw from the study and such a decision will not affect any further treatment options.

11 PROCEDURES INVOLVED

11.1 Study Design

Examine how filter ventilation messaging influences real-world product use, perceptions of and responses to products, and awareness of filter ventilation.

Cigarettes are not smoked in isolation, but in a broader informational context. Thus, the effects of ventilation on responses to product use must be assessed with respect to product communications. We will conduct a field protocol in which various product messaging will be assessed under real-world product use experiences in terms of consumers' ratings of product appeal, risk perceptions, or change cigarette smoking behavior. We hypothesize that messaging will influence filter ventilation awareness and perceptions, but not behavior change.

Filters from these sessions will be used to examine within-cigarette compensatory smoking behaviors (e.g., vent blocking; mouth level exposure).[114-116]

11.2 Treatment

This study will use two types of cigarettes. On set of cigarettes are commercially available Marlboro cigarettes (Philip Morris USA, Richmond, VA), all combustible King size (83mm) cigarettes consisting of filler, filter paper, tipping paper, cigarette paper, tipping glue and seam glue. Specific varieties are listed in the table. Products will be sourced at retail from local outlets.

Alternatively, participants may receive investigational "roll your own" (RYO) cigarettes that will be prepared in the laboratory. These cigarettes will be made to match the commercially available Marlboro cigarettes. These cigarettes will be prepared with conventional tobacco (e.g., Good Stuff) rolled using an automatic rolling machine (e.g., Powermatic III+) and packaged into 20 rod packs. The investigational RYO cigarettes will use ventilated filter tubes (e.g., ~25-37% filter ventilation). The dose of nicotine in these RYO cigarettes will be similar to conventional cigarettes.

Within each pair of products is a nonmenthol and menthol equivalent. Participants who report regularly smoking menthol cigarettes will receive the menthol versions for the study.

Variety	Vent %	Filter length (mm)	Tobacco weight (mg)
Special Blend Smooth Mellow	30.6	27	625.1
Smooth Fresh Menthol	37.6	27	630.8

Additionally, cigarettes will be paired with messaging about filter ventilation. This message will be affixed to the front exterior of each package provided to participants.

- No Message (e.g., unaltered cigarette pack).
- Neutral Message: "Nothing about this product's color or name means that it will protect a smoker from the health risks of smoking."
- Compensation Message: "This product has a ventilated filter. Filter vents increase how deeply a smoker inhales without them knowing, which can increase the health risks of smoking."
- Blocking Message: "This product has a ventilated filter. Be sure not to block the vent holes with your fingers or lips, which can increase the health risks of smoking."

With these conditions, 'no message' serves as a true control (smoking as normal), while the neutral message serves as a control message to determine if added messaging impacts behavior/perceptions, even if that message is not informational. The compensation and blocking messages will determine if added messaging about the health risks of filter ventilation affect behavior/perceptions, and which type of message has the greater impact.

11.3 Study Procedures

The proposed study is a between-subjects design in which participants will be randomized to 1 of 4 conditions for 2 weeks.

- No Message (e.g., unaltered cigarette pack).
- Neutral Message: "Nothing about this product's color or name means that it will protect a smoker from the health risks of smoking."
- Compensation Message: "This product has a ventilated filter. Filter vents increase how deeply a smoker inhales without them knowing, which can increase the health risks of smoking."
- Blocking Message: "This product has a ventilated filter. Be sure not to block the vent holes with your fingers or lips, which can increase the health risks of smoking.

Data will be collected in three remote video sessions and via EMA conducted over 2 weeks. Each study session is expected to take 0.5 hours. For each condition, active data collection is expected to take no more than 15 minutes. Study materials (cigarettes, CO monitor, containers for cigarette filter collection, scales) will be mailed to, delivered, or picked up by participants. Session 1 will involve confirmation of receipt of study materials, questionnaires, and training on procedures. Then, participants will track their product use via EMA app (REDCap) for 2 weeks, with two remote sessions via videoconference for additional questionnaires.

Informed Consent. An initial videoconferencing session will be used for informed consent. Consent will be obtained through the REDCap (Research Electronic Data Capture) system used for data collection. REDCap is a secure web-based application that supports data capture and management for research studies. The Investigator and Research Associate will design the study specific consent and upload the most recent CRS versions to the REDCap system. A secure link will be sent to each participant prior to the start time of the study. Research staff will guide the participant form, provide time to read the consent, and answer any questions. Participants and staff will be able to electronically sign, data, and submit the consent in real-time. Once the consent is submitted, it is automatically saved on RPCI protected servers. Access to this folder is restricted to authorized users. Standard protocols for data encryption (via Credant) when using laptops and USB drives will be followed.

In the event of REDCap being inaccessible for a study visit, .pdf files or paper copes of the consent will be provided to the participants and the participants will be able to sign and return or submit a photo of the signed copy.

The participant will then be randomized to 1 of 4 message conditions (No message, Neutral message, Compensation message, Blocking message) and arrangements will be made to mail, deliver, or have participants pick up study materials (study cigarettes with pack messages, CO

monitor, scales, butt collection materials, shipping materials, etc.). Participants will be provided with two weeks of materials.

Session 1. Session 1 will occur upon receipt of study materials by the participant. Participants will complete a baseline intake questionnaire including smoking and tobacco use history, nicotine dependence scales, SCQ, TRIRISK, delay discounting, respiratory symptoms, and knowledge, attitudes, and beliefs about filter vents. In addition, participants complete questionnaires on message perceptions (response to messaging, health risk, purchase intention) for all pack messages. Questionnaires also will be used to get baseline assessments of the user's usual brand of cigarettes (Duke Sensory Scale, Product Evaluation Scale, Hedonic Attribute Scale). Participants will be instructed to record each smoking event using the EMA app provided (described in more detail below) and to retain all spent cigarette butts and unused product. Participants will be informed that they are free to use other tobacco products (though they will not be provided as part of the study), and that these should be recorded using EMA. Participants will be provided for cigarettes for a total of two weeks, with the amount determined by normal self-reported weekly consumption rounded to nearest whole pack.

Remote Data Collection. Participants will complete the two-week study remotely using EMA methods. At the conclusion of Session 1, participants will be trained to record their assigned product use via EMA for data collection. Specifically, participants will respond to 5 scheduled questionnaires daily. These questionnaires are designed to assess product consumption, context of use (e.g., location, social situation), and subjective responses (e.g., withdrawal, product evaluation, message attention - more details on surveys provided below). Participants will be prompted to measure their exhaled-air CO level and product weight twice each day using a personal monitor provided to them. Participants will also retain all spent cigarette butts and unused products throughout the two weeks.

Day 3 Check-in: Research assistants will monitor EMA data to ensure the participant is compliant with study procedures. Participants will send a secure text message (via Twilio) or arrange a phone call to discuss the participant's compliance in the initial days of data collection. Participants that are not responding to prompts will be retrained to ensure they understand procedures and warned that compliance must increase to continue participating in the study.

Session 2 will take place one week later (± 2 days) via remote videoconference using an institution-approved software with a password protected meeting (e.g., WebEx, Microsoft Teams, Zoom). The Session 2 videoconference will include the completion of questionnaires on vent awareness, product evaluation, and readiness to quit (similar to Visit 1). Participants will again be asked on message perceptions, but only in relation to their randomly assigned condition.

Session 3 will take place one week later (±2 days) via remote videoconference. The same questionnaires from Session 2 will be administered again. Laboratory staff will guide participants to place all materials (retained filter butts, unused products, unsigned payment receipts) in the provided shipping box. Arrangements will be made for the participant to return materials or for research staff to pick up materials. Participants will be paid for Visit 3 upon verification of returned study materials.

11.4 Data To Be Collected

- **Baseline measures and covariates will assess:**
    - Demographics (age, sex, race/ethnicity, education, income)

  - Tobacco use behaviors (consumption, brand, menthol preference, past quit attempts)
- Delay discounting
- A series of previously used items will assess knowledge and perceptions of filter vents.[113,117]
- Nicotine dependence will be assessed using:
  - Fagerström Test for Nicotine Dependence (FTND[118])
  - PROMIS

Behavioral aspects of cigarette dependence will be assessed using:

- The Glover-Nilsson scale [120,121]
- The different scales are used to capture different dimensions of tobacco dependence.[122]
- Exhaled air CO will be collected by the participants twice each day using a personal CO monitor provided by the researchers. The CO monitors provided are coVita iCo™ Smokerlyzers®, which are intended for research and consumer use and are compatible with a Smartphone or tablet (iOS or Android).

Perceptions of product messaging: In this study, we are interested in risk perceptions, smoking-related expectancies, and behavioral intentions. We will assess risk perceptions for specific products using a risk ladder.[129] More generalized perceptions of risk for cancer are captured using the tripartite risk (TRIRISK) measure, which captures deliberative, affective, and experiential components of risk perception.[130] The adult smoking consequences questionnaire (SCQ) will assess smoking-related expectancies.[103,131] Behavioral intention is assessed using Juster's consumer purchase probability scale, a widely used marketing metric.[132-134] Additional questions will include responses to messaging (e.g., message was powerful, memorable).

Responses to product use will be assed in a number of ways: Response to nicotine dose will be assessed using the Minnesota Nicotine Withdrawal Scale (symptoms of nicotine withdrawal).[135] Cigarette craving in field will be assessed using the Brief QSU commonly used in cue reactivity research. Behavioral economic measures will assess product demand. A delay discounting task will assess preference for immediate reward,[148] while purchase tasks will be used to estimate level and elasticity of demand.[149-151] Sensory measures will be collected using the Duke Sensory Scale and Hedonic Attribute Scale. Drug effect measures include the Product Evaluation Scale and Drug Effects/Liking Scale.

Cigarette tracking via EMA: For the field study, the key outcome is the total number of cigarettes smoked. Participants will be asked to complete REDCap questionnaires on their personal phone (iOS or Android). Participants can use the MyCap application to respond to questionnaires. Additionally, REDCap can interface with Twilio, a secure text-messaging platform, to send study related messages and surveys via SMS (text messaging). Proposed EMA methods are based on established best practices. Participants will complete 5 questionnaires every day. These questionnaires will occur at the same time each day: 11am, 1:30pm, 4pm, 6:30pm, and 9pm. These daily reports will be used to assess cigarette and e-cigarette consumption, and 10 items relating to subjective ratings of nicotine withdrawal (e.g., craving, irritability) and mood (e.g., calm/relax, happy). At 11am only, participants will complete selected items from the Hedonic Attribute Profile and Product Evaluation Scale. At 9pm only, participants will be asked to rate the taste, satisfaction,

enjoyment, and craving relief from the cigarettes they smoked that day. Participants will also be asked to take a CO measurement at this time. At the 1:30 and 6:30 prompts, participants will be asked about situational factors related to use (Location, smoking permitted, with others, activity, craving) and complete the Duke Sensory Evaluation scale. Participants also will be asked to take a picture of their research cigarette pack to ensure compliance. Surveys will be open for 1 hour after the scheduled time for completion. Appendix C demonstrates the EMA schedule and the questions asked at each daily report and pseudo-random prompt. Participants can earn up to $10 for each day of EMA compliance, with compliance being defined as responding to ≥ 4 of 5 daily prompts (up to 14 days, totaling $140). Studies that used similar methods had >90% compliance. [189, 190].

12 WITHDRAWAL OF SUBJECTS

12.1 Anticipated Circumstances Under Which Subjects Will be Withdrawn From the Research Without Their Consent

Participants will be withdrawn from the study if they do not follow the study schedule or requirements. Participants are expected to reach 80% EMA compliance daily (>4 of 5 prompts). If a participant fails to reach 80% compliance for 3 consecutive days, that participant will be warned and retrained. If the participant continues to be noncompliant for 3 additional days, they will be withdrawn from the study. Failure to respond to any study prompts (0% compliance) for three consecutive days will result in withdrawal.

12.2 Procedures That Will be Followed When Subjects Withdraw From the Research, Including Partial Withdrawal From Procedures With Continued Data Collection

The participants will only be paid for the completed study sessions and then will be dismissed from the study.

13 RISKS TO SUBJECTS

13.1 Foreseeable Risks

Answering questionnaires pose none to minimal risk. In the event a question causes any type of distress, information will be provided to identify psychological resources available to the participant. There is no to minimal risk for providing breath samples for measurement of carbon monoxide (CO). When providing materials to participants by mail, delivery confirmation with signature will be used to confirm the correct person receives the materials.

Cigarette smoking.

Since we are using commercially available cigarettes, the side effects of the cigarettes used in this study would be similar to the use of other commercial cigarette products, including those the participants smoke themselves. Participants could experience an increased risk for mouth sores, gum disease and tooth loss, nausea or stomach aches, vomiting, or high blood pressure. Some people who use cigarettes may experience irritation of the mucosal membranes of the upper respiratory tract (i.e., the membranes that line the mouth and throat), but as the participants in this study are already regular users, we do not think that this is likely to occur.

- Rare but Serious Side Effects: Those that occur in less than 5% of persons who use nicotine products.
    - Mouth irritation
    - Severe sore throat
    - Irregular heartbeat or rapid heartbeat
- More common but less Serious Side Effects: Those that occur in less than 10-30% of persons who use nicotine products.
    - Indigestion or heartburn
    - Nausea, vomiting, dizziness, diarrhea, or weakness

14 POTENTIAL BENEFITS TO SUBJECTS

14.1 Potential Benefits

There are no direct benefits to taking part in this study.

14.2 Indication of No Direct Benefits

There are no direct benefits to taking part in this study. This research has potential to inform FDA regulation of tobacco products.

15 SHARING OF RESULTS WITH SUBJECTS

All analyses will be completed as a group. Though the goal is to publish the overall results in a scientific journal made available to the public, no individual's results or information will be shared either with the subject or public. Participants may receive overall final results of the study by mail if desired.

16 ECONOMIC BURDEN TO SUBJECTS

16.1 Costs that Subjects May be Responsible for Because of Participation in the Research

There are no costs to the participant associated with study participation.

17 PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF SUBJECTS

17.1 Protection of the Subjects' Privacy Interests

Participants will only interact with the research coordinator conducting the interview.

17.2 Steps Taken to Make the Subjects Feel at Ease with the Research Situation in Terms of the Questions Being Asked and the Procedures Being Performed. "At Ease" Does Not Refer to Physical Discomfort, but the Sense of Intrusiveness a Subject Might Experience in Response to Questions, Examinations, and Procedures.

The research coordinators will administer and review an informed consent document, explaining all components of the research study. Participants are only encouraged to verbally agree to the conditions in the consent only if they are completely comfortable with the study design and

procedures. Participants will have the opportunity to ask questions at any point during the study and may withdraw at any time.

17.3 How the Research Team is Permitted to Access Any Sources of Information About the Subjects

The research team is only permitted to access sources of information provided by the participant.

18 VULNERABLE POPULATIONS

N/A.

19 DATA AND SPECIMEN BANKING

19.1 Data Banking

For purposes of this research, we will collect the following identifiable information:

- Participant Name – to verify identification
- Date of birth - to verify age
- Telephone number - to facilitate contact for scheduling
- Mailing address - to send study materials
- Email address - to facilitate contact for scheduling and videoconference access
- Identifiable information will be retained in a separate Excel file from the analytic dataset. The only link to identifiable information will be via a unique ID number.

All questionnaires are administered via REDCap, housed at RPCI. All data files will be electronic, including only the unique subject ID. All datafiles will be stored on the Cancer Prevention server (\\CancerPrev\CancerPrev$\HealthBehavior\TobaccoLab). Access to this folder is restricted to authorized users. Standard protocols for data encryption (via Credant) when using laptops and USB drives will be followed. Twilio is a third-party web service that has been integrated into REDCap to send survey invites and SMS messages to participants via text. All participant data is stored in REDCap, and Twilio is only used to send the text and survey link. When the respondent presses the link, their browser on their smart phone will open to complete the survey in the secure website or reed any sent messages. When a participant provides permission for study staff to send the daily survey invite by SMS (text), the Twilio program within REDCap will provide that functionality. When a participant responds, Twilio will relay the information back to REDCap. Once a participant completes a daily survey, the data are sent through Twilio servers to REDCap. Data are stored in the REDCap database, not in Twilio, so that the data are encrypted and secured. Twilio does not maintain a log of outgoing/incoming messages or calls.

19.2 Data Procedures

All data files will be electronic, including only the unique subject ID. All datafiles will be stored on the Cancer Prevention server (\\CancerPrev\CancerPrev$\HealthBehavior\TobaccoLab). Access to this folder is restricted to authorized users. Standard protocols for data encryption (via Credant) when using laptops and USB drives will be followed.

19.3 Data Protocol for Multi-Site Study

All sites will input data from surveys and interviews directly into the RedCap database housed at RPCI. RPCI will conduct all data analysis.

Note: All investigator or analyzing research laboratories housing research samples need to maintain current Temperature Logs and study-specific Sample Tracking and Shipping Logs. The Principal Investigator/Laboratory Manager must ensure that the stated lab(s) have a process in place to document the receipt/processing/storage/shipping of study-related samples/specimens. This is required for all studies collecting clinical samples.

20 SAFETY REPORTING

Unanticipated Problems

An Unanticipated Problem (UP) is any incident, experience, or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given:
    - The research procedures that are described in the study-related documents, including study deviations, as well as issues related to compromise of participant privacy or confidentiality of data.
    - The characteristics of the participant population being studied.
- Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).

Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized and if in relation to an AE is also deemed Serious as deemed below:

Serious Adverse Events

A serious adverse event (SAE) is any adverse event (experience) that in the opinion of either the investigator or sponsor results in **ANY** of the following:

- Death
- A life-threatening adverse event (experience). Any AE that places a participant or participants, in the view of the Investigator or sponsor, at immediate risk of death from the reaction as it occurred. It does NOT include an AE that, had it occurred in a more severe form, might have caused death.
- Inpatient hospitalization or prolongation of existing hospitalization (for > 24 hours).
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions.
- A congenital anomaly or birth defect.
- Important Medical Event (IME) that, based upon medical judgment, may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

Reporting Unanticipated Problems

Unanticipated problem reporting will begin at the time of participant consent. The Reportable New Information (RNI) Form will be submitted to the CRS Quality Assurance (QA) Office within 1 business day of becoming aware of the Unanticipated Problem. After review, the CRS QA Office will submit the RNI to the IRB.

When becoming aware of new information about an Unanticipated Problem, submit the updated information to the CRS QA Office with an updated Reportable New Information Form. The site Investigator or designated research personnel will report all unanticipated problems to the IRB in accordance with their local institutional guidelines.

21 DATA MANAGEMENT AND CONFIDENTIALITY

21.1 Identifiable Information Necessary for Research

For purposes of this research, we will collect the following PHI:

- Participant Name – to verify identity
- Date of birth - to verify age
- Telephone number - to facilitate contact for scheduling
- Mailing address - to send study appointment materials
- Email address (optional) - to facilitate contact
- Identifiable Information protocol

Identifiable information will be retained in a separate Excel file from the analytic dataset. The only link to identifiable information will be via a unique ID number in order of participation.

All data files will be electronic, including only the unique subject ID. All data files will be stored on the Cancer Prevention server (\\CancerPrev\CancerPrev$\HealthBehavior\TobaccoLab). Access to this folder is restricted to authorized users. Standard protocols for data encryption (via Credant) when using laptops and USB drives will be followed.

Remote participation will be facilitated using videoconferencing software approved by the institution site, such as Webex, Zoom, or Microsoft Teams. All videoconferencing will be conducted using institution-affiliated logins and password protected meetings. Cisco WebEx, for which Roswell Park has a license, will be used by Roswell Park staff. This software allows for secure videoconferencing. For this study, participants will receive information to access a specific videoconference as a predetermined time with a study research assistant. Videoconferences will be recorded to confirm compliance with study procedures.

21.2 Plan to Protect Research Data

All data files will be electronic, including only the unique subject ID. All data files will be stored on the Cancer Prevention server (\\CancerPrev\CancerPrev$\HealthBehavior\TobaccoLab).

21.3 Data File Security

Standard protocols for data encryption (via Credant) when using laptops and USB drives will be followed.

21.4 Data File Access

Access to this folder is restricted to authorized users.

21.5 Protocol for Data Accessed by Multiple Personnel

Standard protocols for data encryption (via Credant) when using laptops and USB drives will be followed.

21.6 Plan to Destroy Identifiers

Identifiers will be deleted at the earliest possible opportunity.

21.7 Identifiable Information to be Reused or Disclosed to any Other Person or Entity

Access to this folder is restricted to authorized users.

21.8 Data Security Plan

Identifiable information will be retained in a separate Excel file from the analytic dataset. The only link to PHI will be via a unique ID number in order of participation.

All data files will be electronic, including only the unique subject ID. All datafiles will be stored on the Cancer Prevention server (\\CancerPrev\CancerPrev$\HealthBehavior\TobaccoLab). Access to this folder is restricted to authorized users. Standard protocols for data encryption (via Credant) when using laptops and USB drives will be followed.

22 STATISTICAL PLAN

22.1 Data Analysis Plan

The analysis of EMA data will be analyzed using a linear mixed model with fixed effects for vent message (product design, color/name), as well as sex and other tobacco product strata (cigarettes only or dual use). The effect of packaging will be tested using a Bonferroni-corrected type-I error rate of 0.008 (0.05/6) to account for all possible pairwise comparisons of packaging types. Data from the field-study (e.g., change in product responses, risk, TNE, aldehyde-DNA adducts) will be analyzed using linear regression with terms in the model for vent message (no message, neutral, compensation, blocking), sex, and other tobacco product use.. Categorical outcomes for the field-study will be analyzed using logistic regression. As exploratory approaches, we will use time-varying effects models (TVEMs) to explore the effect of message condition on smoking behavior (product compliance), craving, risk perception, and quit intention in the EMA data.[191, 192] TVEMs have been used previously to examine treatment effects on craving [193] and relapse.[194] TVEMs will provide daily effect sizes, thereby allowing us to examine whether treatment effects (and relationships with other predictors) change over time (i.e., early vs. later in product switching). Responses at Visit 1 can be treated as time invariant predictors and mCEQ from EMA can be treated as time-varying predictor (and/or outcome) of product use.

We will enroll a total sample size of 300 subjects and assume a 20% drop-out rate with uniform drop-out from Visit 1 to Visit 3. This will result in a sample size of 300 subjects for Visit 1, 270 subjects for the first week of the field study, and 240 subjects for the end of field study. Our sample size was determined to have adequate power for the field study, For the field study, we hypothesize a 25% difference between conditions, corresponding to a 3.9 CPD difference. Assuming a standard deviation of 7.6,[195] a sample size of 240 subjects will provide 95% power to detect a significant difference between ventilation conditions at the 0.05 level and 80% power to detect a significant difference between packaging conditions with a Bonferroni-corrected type-I error rate of 0.008.

mCEQ is scored using an established algorithm.[96] This results in 3 subscales (Psychological Reward, Relief, Reward) and 2 single items (Aversion, Respiratory sensation). Scores range from 1-7.

CO boost is defined as the difference between pre-smoking exhaled CO and post-smoking exhaled O. This is typically a positive value.

23 COMMUNITY-BASED PARTICIPATORY RESEARCH

N/A.

24 MULTI-SITE RESEARCH

24.1 Communication and Protocol Approval at Multi-Site Centers

Roswell Park will be the IRB of record for this study. Accruals will occur at Roswell Park, Harvard School of Public Health (Site PI: Vaughan Rees), and Medical University of South Carolina (Site PI: K Michael Cummings). Each participating site will enter into a reliance agreement with the Roswell Park IRB, with appropriate inclusion of local information.

25 RESOURCES AVAILABLE

The PI has over a decade of experience in behavioral research. We are recruiting from the general population of Erie/Niagara. The total population over 21 is approximately 1 million, of which 15% smoke, we anticipate no issues in accruing 100 smokers.

26 PRIOR APPROVALS

This study is funded by National Cancer Institute. P01 CA217806 (PI: Dorothy Hatsukami, University of Minnesota).

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28 APPENDICES/ SUPPLEMENTS

Appendix A: Recruitment Materials

Print ad copy.

[insert site logo]

RESEARCH PARTICIPANTS NEEDED

Researchers at [insert study site] are searching for **smokers to participate in a two-week field study** for an important research project.

Participation involves two weeks of remote data collection and three videoconferencing sessions. Remote data collection involves 5 daily questionnaires on product use.

Must be **21-69 years old daily cigarette smokers** to participate.
Participants will be compensated for their time.

If interested, please contact
[insert site contact number here]
And ask for the VENT study

Roswell Park Protocol Number: I 757820

Referral Coupon Example

VENT Study Coupon

Code:

Return of this coupon ensures the referrer to $10
after the referral successfully completes the VENT Study

Date Distributed:

Date Returned:

Signed (Research Coordinator):

Roswell Park Protocol Number: I 757820

Prior Participant Recruitment Letter

[to be printed on [insert site]letterhead]

Dear [*insert name*],

We are contacting you because you previously completed study with us, and asked to be contacted in the future if another research opportunity became available.

We are looking for regular cigarette smokers to participate in an important research project. The purpose of the study is to examine the impact of messaging about filter ventilation, a common design feature of cigarettes.

To do this, we are asking people to participate in a study involving two weeks of remote data collection and three videoconferencing sessions in which you will be asked to use specific cigarettes. During the first videoconference session, we would ask you to answer questionnaires on your smoking behavior and train you on remote data collection procedures. During remote data collection, we will ask you to respond to 5 questionnaires about product use, situational factors (location, social situation) and how you're feeling. We hope findings from this study can inform the regulation of cigarette products by the federal or state government.

This research has received ethics clearance from the Roswell Park Institutional Review Board and all the information you provide will be kept strictly confidential. Only the investigators directly associated with the study will have access to this information. This study is funded by the National Cancer Institute, National Institutes of Health, and the investigators have no affiliations with any tobacco or pharmaceutical company.

If you are interested, please contact insert site contact number], and ask for the VENT Study. You may also email [insert site email] with a good time to call you.

Sincerely,

[*insert name*]
[insert title] [insert location] [insert study site]

Roswell Park Protocol Number: I 757820

Appendix B: Eligibility Screener

Core Eligibility Screener

1. Please enter your name.
_____

2. Please enter your phone number, starting with the area code.
___ ___ ___ - ___ ___ ___ - ___ ___ ___ ___

3. Do you currently use tobacco products? By currently, we mean any use at all in the last month (30 days)
___ Yes
___ No

4a. Which products have you used in the past 30 days? Please check all that apply.
___ Cigarettes (proceed to 4b)
___ Cigars
___ Cigarillos
___ Clove Cigarettes
___ Herbal Cigarettes
___ Bidis
___ Pipe Tobacco
___ Roll Your Own
___ Chewing Tobacco
___ Moist Snuff
___ Snus
___ E-Cigarettes
___ Vapes
___ No products. I am not a smoker. (Ineligible)

4b. Are your current cigarettes made by a company or roll your own?
___ Manufactured
___ Roll Your Own

5. Which brand of cigarettes do you currently smoke? Please be as specific as possible (e.g. Marlboro gold 100s box).
_____ (needs to smoke factory-made filtered cigarettes)

Note to interviewer: check brand variety against lab database. Eligible if ventilation >10%. Common ineligible brands: Newport menthol; Newport red; Marlboro Black. If data unavailable, ask participant to bring a pack of their own cigarettes to Session 1 for confirmation.

6. Have you used any Nicotine Replacement medication such as the patch, gum, lozenge, spray, or inhaler in the past 30 days?
___ Yes
___ No

7. Do you smoke cigarettes some days or every day?
___ Every Day
___ Some Days
___ Not at all

8. How many cigarettes do you smoke per day? Please enter a number.
___ 5 or more
___ Less than 5

9. How long have you been smoking?
___ More than 1 year
___ Less than 1 year

10. Have you tried to quit smoking in the past 30 days?
(More than a 24-hour time period without smoking)
___ Yes
___ No

11. Are you seriously thinking of quitting smoking?
___ Yes, within the next 30 days
___ Yes, within the next 6 months
___ No, not thinking of quitting

12. What sex do you identify with?
___ Male
___ Female
___ Undetermined
___ Refused

13. What is your age? Please enter a number (years).
_____ (Eligible = 18-69 years old)

14. Please describe your overall health.
___ Excellent
___ Very Good
___ Good
___ Fair
___ Poor

15. Please describe your overall mental health.
___ Excellent
___ Very Good
___ Good
___ Fair
___ Poor

16a. How often did you have a drink containing alcohol in the past year?
Never (0)
Monthly or less (1)
Two to four times a month (2)
Two to three times a week (3)
Four or more times a week (4)

16b. How many drinks did you have on a typical day when you were drinking in the past year?
None, I do not drink (0)
1 or 2 (0)
3 or 4 (1)
5 or 6 (2)
7 to 9 (3)
10 or more (4)

16c. How often did you have six or more drinks on one occasion in the past year?
Never (0)
Less than monthly (1)
Monthly (2)
Weekly (3)
Daily or almost daily (4)
16total. Sum responses to 16a-c (score must be <7 for inclusion)

17. How many times in the past month have you consumed cannabis/marijuana/THC?
_____ (>5 = Ineligible)

18. How many times in the past month have you used an illegal drug or used a prescription medication for non-medical reasons? Please enter the number below.
_____ (>1 = Ineligible)

19. Are you currently involved in any other Roswell Park research studies?
___ Yes (place on wait list if otherwise eligible; can begin after involvement in other study ends)
___ No

These next few questions ask about rules of using tobacco inside your home. Please think about everyone who might be in your home including children, adults, visitors, guests, or workers. For tobacco products that are burned, such as cigarettes, cigars, pipes or hookah, which statement best describes the rules about smoking a tobacco product inside your home?

1 It is not allowed anywhere or at any time inside my home

2 It is allowed in some places or at sometimes inside my home

3 It is allowed anywhere and at any time inside my home

For electronic cigarette products, such as e-cigarettes, vape pens, tanks, mods, JUUL, which statement best describes the rules about vaping inside your home?

1 It is not allowed anywhere or at any time inside my home

2 It is allowed in some places or at sometimes inside my home

3 It is allowed anywhere and at any time inside my home

If Ineligible:
Unfortunately, you are ineligible for the study. However, we thank you for your interest and hope you have a great day.

If Eligible:
You are eligible for the study! I'd like to give you some more information before asking whether you'd like to participate. The purpose of the study is to examine the relationship of certain cigarette design features, such as pack messages, to exposure and consumer perceptions. You will be asked to take part in a two-week field experiment where you will be assigned to smoke specific cigarettes and track your use. The study is done remotely, so we will send you all study materials and text/email questionnaires to you. Three times during the field experiment, you will be asked to videoconference with a research assistant for approximately 30 minutes. In addition, you will be asked to respond to 5 brief questionnaires daily to track your cigarette use and report on study cigarettes.

This project has received ethics clearance from the Roswell Park Comprehensive Cancer Center Institutional Review Board and all the information you provide will be kept strictly confidential. Only the investigators directly associated with the study will have access to this information and it will be destroyed once the study is completed.

I realize I've given you a lot of information- do you have any questions about the study?

Would you like to participate in the study?

If no: Thank you and goodbye.
If yes: Great.

We'd like to get your mailing address and email address so we can send you additional information about the study. Are you willing to provide one or both?

Mailing Address:

_____

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Email:

_____
___

What day(s) would be the best to reach you? Please check all that apply.
___ Monday
___ Tuesday
___ Wednesday
___ Thursday
___ Friday
___ Saturday
___ Sunday

What time of day would be best to reach you? Please check all that apply.
___ Morning (8am – 12pm)
___ Afternoon (12pm – 4pm)
___ Evening (4pm – 8pm)

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Appendix C: Study Questionnaires

DEMOGRAPHICS AND SMOKING HISTORY QUESTIONNAIRE

1. Age

☐☐

2. Are you of Hispanic, Latino, or Spanish origin? (check all that apply)

- ☐ Yes, Hispanic or Latino
- ☐ NOT Hispanic or Latino
- ☐ Unknown / Not Reported

3. What is your race? (check all that apply)

- ☐ American Indian, Alaskan Native
- ☐ Asian
- ☐ Native Hawaiian / Pacific Islander
- ☐ Black/African American
- ☐ White
- ☐ More Than One Race
- ☐ Unknown / Not Reported

4. Gender

- ☐ Female
- ☐ Male

5. What is your current marital status?

- ☐ Never Married
- ☐ Married for the First Time
- ☐ Remarried
- ☐ Separated
- ☐ Divorced
- ☐ Widowed

6. What is the highest level of education you completed?

- ☐ 8th grade or less
- ☐ Some High School
- ☐ High School Graduate/Equivalent
- ☐ Some College/2-year Degree
- ☐ College Graduate/4-year Degree
- ☐ Graduate or Professional Degree

7. Are you currently a student?

- ☐ Yes, studying full-time
- ☐ Yes, studying part-time
- ☐ No, I am not currently undertaking formal study

8. What is your annual household income (from all sources)?

- ☐ Less than $10,000
- ☐ $10,000 to $14,999
- ☐ $15,000 to $19,999
- ☐ $20,000 to $24,999
- ☐ $25,000 to $29,999
- ☐ $30,000 to $34,999
- ☐ $35,000 to $39,999

☐ $40,000 to $49,999
☐ $50,000 to $74,999
☐ $75,000 to $99,999
☐ $100,000 to $149,999
☐ $150,000 to $199,999
☐ $200,000 or more
☐ Prefer not to say

9. What is your current employment status?
☐ Regular full-time work (daytime shift: 6 AM to 6 PM)
☐ Regular full-time work (evening or night shift)
☐ Part-time work (typically consistent shift)
☐ Casual work (irregular or informal work)
☐ Looking for paid work
☐ A homemaker or caregiver not looking for paid work
☐ Retired
☐ Unable to work due to health reasons
☐ Unable to work due to other reasons

10. Have you smoked at least 100 cigarettes in your entire life? (100 CIGARETTES = APPROXIMATELY 5 PACKS)
☐ Yes **(GO TO A2)**
☐ No

11. How old were you when you smoked your first cigarette? (XX years old)
☐☐ years old

12. Do you now smoke cigarettes every day, some days, or not at all?
☐ Every Day **(GO TO B1)**
☐ Some Days
☐ Not At All

13. On the average, about how many cigarettes do you now smoke each day?
(ONE PACK USUALLY EQUALS 20 CIGARETTES. IF CONVERTING PACKS TO CIGARETTES, ALWAYS VERIFY CALCULATION WITH RESPONDENT.)
☐☐ Cigarettes Per Day

14. What is your usual brand of cigarettes? Please be specific. (For example, Marlboro Gold, Menthol 100s) _____

15. How long (in years) have you smoked this brand of cigarette? (If you have smoked this brand of cigarette for less than 1 year, enter 0.)

How important to you are each of the following characteristics of your cigarette brand 1='Not at all' to 10='Extremely'.
Brand name
Color
Pack design/looks/visuals
Length (e.g., King, 100, 120)

Pack type (e.g., soft, hard)
Price
Taste

Behavioral aspects of cigarette/vaping dependence will be assessed using:

Glover-Nilsson Scale

Please indicate your choice by circling the number that best reflects your choice.

	0=Not at all	**1=Somewhat**	**2=Moderately**	**3=Very much**	**4=Extremely**
16. My cigarette[vaping] habit is very important to me					
17. I handle and manipulate my cigarette[vape] as part of the ritual of smoking					

Please indicate your choice by circling the number that best reflects your choice.

	0=never	**1=seldom**	**2=sometimes**	**3=often**	**4=Always**
18. Do you place something in your mouth to distract you from smoking[vaping]?					
19. Do you reward yourself with a cigarette [vape] after accomplishing a task?					
20. If you find yourself without cigarettes [vape], will you have difficulties in concentrating before attempting a task?					
21. If you are not allowed to smoke [vape]in certain places, do you then play with your cigarette					

pack [device] or a cigarette [vape]?					
22. Do certain environmental cues trigger your Smoking[vaping], e.g., favorite chair, sofa, room, car, or drinking alcohol?					
23. Do you find yourself lighting up a cigarette [vaping] routinely (without craving)?					
24. Do you find yourself placing an unlit cigarette [vape] or other objects (pen, tooth pick, chewing gum, etc.) in your mouth and sucking to get relief from stress, tension or frustration, etc.)?					
25. Does part of your enjoyment of smoking [vaping] come from the steps (ritual) you take when lighting up?					
26. When you are alone in a restaurant, bus terminal, party, etc., do you feel safe, secure, or more confident if you are holding a cigarette [vape]?					

VENT AWARENESS

1. What makes the filters on Light cigarettes different than the filters on Regular cigarettes?

2. Have you ever seen or heard that one or more rings of small holes are on the filters or some cigarettes?

- ☐ Yes (Go to 2b)
- ☐ No (Go to 3)
- ☐ Don't Know / Not Sure (Go to 3)

2b. How do you know about these holes?

- ☐ Saw them
- ☐ Read about them in the news or magazine
- ☐ Saw a television advertisement about them
- ☐ Saw or heard a news report about them.

3. Did you ever try to block the filter holes on cigarettes?

- ☐ Yes (Go to 3b)
- ☐ No (Go to 4)

4. At the present time, do you block holes when you smoke?

- ☐ Yes
- ☐ No
- ☐ Don't Know

5. Do you think that blocking filter holes would make a cigarette taste stronger, milder, or have no effect on taste?

- ☐ A lot stronger
- ☐ Moderately stronger
- ☐ A little stronger
- ☐ No effect
- ☐ A little milder
- ☐ Moderately milder
- ☐ A lot milder
- ☐ Don't know

6. Do you think that blocking filter holes would increase, decrease, or have no effect on the tar a smoker gets from these cigarettes?

- ☐ Greatly increase
- ☐ Moderately increase
- ☐ Slightly increase
- ☐ No effect
- ☐ Slightly decrease
- ☐ Moderately decrease
- ☐ Greatly decrease
- ☐ Don't know

7. Do you think that blocking filter holes would increase, decrease, or have no effect on the nicotine a smoker gets from these cigarettes?

- ☐ Greatly increase
- ☐ Moderately increase
- ☐ Slightly increase
- ☐ No effect

- ☐ Slightly decrease
- ☐ Moderately decrease
- ☐ Greatly decrease
- ☐ Don't know

TRIRISK [cancer-specific] -- presentation order should be randomized

1. On a scale from 0 to 100 %, how would you rate the probability that you will develop cancer in the future?
2. How likely is it that you will get cancer at some point in the future? [7-point scale (likely–unlikely)]
3. The way I look after my health means that my odds of getting cancer in the future are: [7-point scale (very low–very high)]

*For the following items, indicate whether you agree or disagree with the statement. [*7-point scale (strongly disagree-strongly agree)*]*

4. When I think carefully about my lifestyle, it does seem possible that I could get cancer:
5. If I look at myself as if I was a doctor, I realize that my behavior puts me at risk of getting cancer.
6. I feel very vulnerable to cancer.
7. I am confident that I will not get cancer.
8. I would be lying if I said "There is no chance of me getting cancer."
9. My first reaction when I hear of someone getting cancer is "that could be me someday."

10. How do you think your chance of developing cancer in the future compares to the average person of your gender and age? [7-point scale (much lower-much higher)]

*For the following items, rate on a scale from Not at all to extremely. [*7-point scale (not at all-extremely)*]*

11. How worried are you about developing cancer in the future?
12. How fearful are you about developing cancer in the future?
13. How nervous are you about developing cancer in your lifetime?
14. When you think about cancer for a moment, to what extent do you feel fearful?
15. When you think about cancer for a moment, to what extent do you feel worried?
16. When you think about cancer for a moment, to what extent do you feel anxious?
17. How concerned are you about developing cancer in your lifetime?
18. How easy is it for you to imagine yourself developing cancer in the future?

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PERCEIVED HEALTH RISK RATING: BASELINE

Based on using your usual brand cigarettes indicate what you believe your risk is for developing the following health problems on this scale from 1 to 10.

1 2 3 4 5 6 7 8 9 10

Very Low Risk of Disease — **Very High Risk of Disease**

1. Lung Cancer _____
2. Emphysema _____
3. Bronchitis _____
4. Other Cancers _____
5. Heart Disease _____
6. Risk of Addiction _____
7. Stroke _____
8. Mouth Cancer _____
9. Tooth Loss _____

Minute Discounting 1000 92dd

Which would you rather have?
$500 now $1000 in 3 weeks

Which would you rather have?
$500 now $1000 in 1 day

Which would you rather have?
$500 now $1000 in 2 years

Which would you rather have?
$500 now $1000 in 4 hours

Which would you rather have?
$500 now $1000 in 4 days

Which would you rather have?

$500 now $1000 in 4 months

Which would you rather have?
$500 now $1000 in 8 years

Which would you rather have?
$500 now $1000 in 2 hours

Which would you rather have?
$500 now $1000 in 9 hours

Which would you rather have?
$500 now $1000 in 2 days

Which would you rather have?
$500 now $1000 in 1.5 weeks

Which would you rather have?
$500 now $1000 in 2 months

Which would you rather have?
$500 now $1000 in 8 months

Which would you rather have?
$500 now $1000 in 4 years

Which would you rather have?
$500 now $1000 in 18 years

Which would you rather have?
$500 now $1000 in 1 hour

Which would you rather have?
$500 now $1000 in 3 hours

Which would you rather have?
$500 now $1000 in 6 hours

Which would you rather have?
$500 now $1000 in 12 hours

Which would you rather have?
$500 now $1000 in 1.5 days

Which would you rather have?
$500 now $1000 in 3 days

Which would you rather have?
$500 now $1000 in 1 week

Which would you rather have?
$500 now $1000 in 2 weeks

Which would you rather have?
$500 now $1000 in 1 month

Which would you rather have?
$500 now $1000 in 3 months

Which would you rather have?
$500 now $1000 in 6 months

Which would you rather have?
$500 now $1000 in 1 year

Which would you rather have?
$500 now $1000 in 3 years

Which would you rather have?
$500 now $1000 in 5 years

Which would you rather have?
$500 now $1000 in 12 years

Which would you rather have?
$500 now $1000 in 25 years

BSCQ-A [*0–9 Likert scale Not at all – Extremely likely]*

1. Smoking calms me down when I feel nervous.
2. When I'm feeling irritable, a smoke will help me relax.
3. When I'm angry, a cigarette can calm me down.
4. Smoking a cigarette energizes me.
5. A cigarette can give me energy when I'm bored and tired.
6. The more I smoke, the more I risk my health.
7. By smoking I risk heart disease and lung cancer.
8. I will enjoy the flavor of a cigarette.
9. When I smoke, the taste is pleasant.
10. I enjoy the taste sensations while smoking.
11. I feel more at ease with other people if I have a cigarette.
12. Smoking helps me enjoy people more.
13. I feel like part of a group when I'm around other smokers.

14. Smoking keeps my weight down.
15. Smoking helps control my weight.
16. Cigarettes keep me from eating more than I should.
17. Smoking will satisfy my nicotine cravings.
18. Nicotine ‘‘fits’’ can be controlled by smoking.
19. Smoking irritates my mouth and throat
20. My throat burns after smoking.
21. When I am alone, a cigarette can help me pass the time.
22. If I have nothing to do, a smoke can help kill time.
23. I look ridiculous while smoking.
24. Smoking makes me seem less attractive.
25. People think less of me if they see me smoke.

Minnesota Nicotine Withdrawal Scale [0 -4, Not at all – Severe]
Please rate how you have felt over the past 24 hours.
1. Angry, irritable, frustrated
2. Anxious, nervous
3. Depressed mood, sad
4. Difficulty concentrating
5. Increased appetite, hungry, weight gain
6. Insomnia, sleep problems, awakening at night
7. Restless
8. Desire or craving to smoke
9. Constipation
10. Coughing
11. Decreased pleasure from events
12. Dizziness
13. Drowsy
14. Impatient
15. Impulsive

Barrett Impulsivity Scale-11 [0-4 Never – Always]
People differ in the ways they act and think in different situations. This is a test to measure some of the ways in which you act and think. Read each statement and put an X on the appropriate circle. Do not spend too much time on any statement. Answer quickly and honestly.
1. I plan tasks carefully.
2. I do things without thinking.
3. I make-up my mind quickly.
4. I am happy-go-lucky.
5. I don’t “pay attention.”
6. I have “racing” thoughts.
7. I plan trips well ahead of time.
8. I am self-controlled.
9. I concentrate easily.
10. I save regularly.
11. I “squirm” at plays or lectures.

12. I am a careful thinker.
13. I plan for job security.
14. I say things without thinking.
15. I like to think about complex problems.
16. I change jobs.
17. I act "on impulse."
18. I get easily bored when solving thought problems.
19. I act on the spur of the moment.
20. I am a steady thinker.
21. I change residences.
22. I buy things on impulse.
23. I can only think about one thing at a time.
24. I change hobbies.
25. I spend or charge more than I earn.
26. I often have extraneous thoughts when thinking.
27. I am more interested in the present than the future.
28. I am restless at the theater or lectures.
29. I like puzzles.
30. I am future oriented.

CIGARETTE PURCHASE TASK

Think about HOW YOU ARE FEELING RIGHT NOW. The following questions ask how many cigarettes you would smoke if they cost various amounts of money. Assume that:

1. The available cigarettes are your usual brand.
2. You have the same income/savings that you have now and NO ACCESS to any cigarettes or nicotine products other than those offered at these prices.
3. You can smoke without any restrictions and without factoring in what might occur in the next 24 hours related to your participation in the study
4. You would smoke the cigarettes that you request at this time, not save or stockpile cigarettes for a later date.
5. You may not give any of the products you purchase away.

Be sure to consider each price increment carefully.

1. How many cigarettes would you smoke in 24 hours if they were	*FREE?*	_____
2. How many cigarettes would you smoke in 24 hours if they were	**1¢ each?**	_____
3. How many cigarettes would you smoke in 24 hours if they were	**2¢ each?**	_____
4. How many cigarettes would you smoke in 24 hours if they were	**3¢ each?**	_____

5. How many cigarettes would you smoke in 24 hours if they were	**4¢ each?**	_____
6. How many cigarettes would you smoke in 24 hours if they were	**6¢ each?**	_____
7. How many cigarettes would you smoke in 24 hours if they were	**10¢ each?**	_____
8. How many cigarettes would you smoke in 24 hours if they were	**15¢ each?**	_____
9. How many cigarettes would you smoke in 24 hours if they were	**25¢ each?**	_____
10. How many cigarettes would you smoke in 24 hours if they were	**40¢ each?**	_____
11. How many cigarettes would you smoke in 24 hours if they were	**60¢ each?**	_____
12. How many cigarettes would you smoke in 24 hours if they were	**$1 each?**	_____
13. How many cigarettes would you smoke in 24 hours if they were	**$1.50 each?**	_____
14. How many cigarettes would you smoke in 24 hours if they were	**$2.50 each?**	_____
15. How many cigarettes would you smoke in 24 hours if they were	**$4 each?**	_____
16. How many cigarettes would you smoke in 24 hours if they were	**$6 each?**	_____
17. How many cigarettes would you smoke in 24 hours if they were	**$10 each?**	_____
18. How many cigarettes would you smoke in 24 hours if they were	**$15 each?**	_____
19. How many cigarettes would you smoke in 24 hours if they were	**$25 each?**	_____
20. How many cigarettes would you smoke in 24 hours if they were	**$40 each?**	_____
21. How many cigarettes would you smoke in 24 hours if they were	**$60 each?**	_____
22. How many cigarettes would you smoke in 24 hours if they were	**$100 each?**	_____

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5 TRIAL DELAY DISCOUNTING

You will now complete a series of decision-making tasks. You will be asked to make choices between different amounts of money given to you now or after a delay. These are hypothetical choices, but please choose your answer as if the items were to be delivered as described. Each task will start with some brief instructions on the screen. Read these instructions and press the 5 key on the keyboard when you are ready to begin. There are no right or wrong answers in the tasks, just choose which option you prefer in each case. Please take your time and answer thoughtfully. To select the option on the left side of the screen, press the left arrow, and to select the option on the right side of the screen, press the right arrow.

[Task implemented on computer via REDCap]

IN SESSION MEASURES (Administered after each cigarette)

Product Evaluation Scale

Think about your general experience when using the product you just tried.

Please answer the following questions about the product using the scale below [7-point scale, Not at all – Extremely]

Cigarette Product Code: _____

1. Was it satisfying? _____
2. Did it taste good? _____
3. Did it make you dizzy? _____
4. Did it calm you down? _____
5. Did it help you concentrate? _____
6. Did it make you feel more awake? _____
7. Did it reduce your hunger for food? _____
8. Did it make you nauseated? _____
9. Did it make you feel less irritable? _____
10. Did you enjoy the sensations in your mouth? _____
11. Did it immediately reduce your craving for a cigarette? _____
12. Did it relieve withdrawal symptoms? _____
13. Did it relieve the urge to smoke? _____
14. Was it enough nicotine? _____
15. Was it too much nicotine? _____
16. Was it easy to use? _____

17. Were there bothersome side effects? _____
18. Would you be comfortable using the product in public? _____
19. Did you still have a craving for a cigarette after using the product? _____
20. Are you concerned you would become dependent on the product? _____
21. Did you enjoy using the product? _____
22. Would you be willing to use the product long term? _____

JUSTER PURCHASE INTENTION

How likely are you to purchase the product you just tried in the next month?

- ☐ 10 = Certain, practically certain
- ☐ 9 = Almost sure
- ☐ 8 = Very probable
- ☐ 7 = Probable
- ☐ 6 = Good possibility
- ☐ 5 = Fairly good possibility
- ☐ 4 = Fair possibility
- ☐ 3 = Some possibility
- ☐ 2 = Slight possibility
- ☐ 1 = Very slight possibility
- ☐ 0 = No chance, almost no chance

Duke Cigarette Sensory Evaluation [1-7 Not at all – Extremely]

Please rate the puffs you just took. Circle the number that best answers each question.

1. How much did you like the puffs you just took?
2. How satisfying were the puffs you just took?
3. How high in nicotine do you think the puffs were?
4. How similar to your own brand were the puffs?

Using the same scale as above, rate how strong the puffs were in the following places.

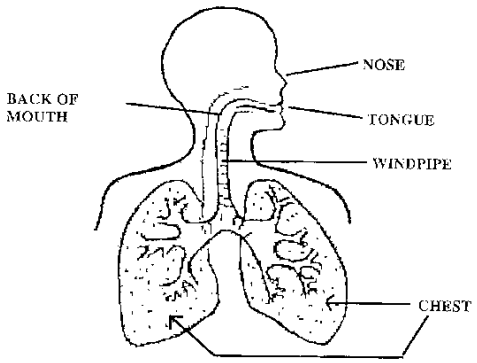
5. Strength of puffs on tongue?

6. Strength of puffs in nose?

7. Strength of puffs in back of mouth & throat?

8. Strength of puffs in windpipe?

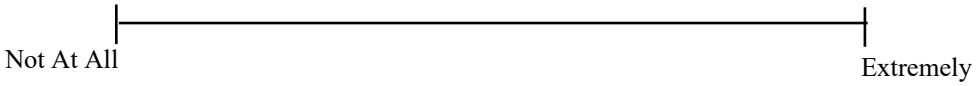
9. Strength of puffs in chest?



DRUG EFFECTS / LIKING SCALE

Place a vertical line at the point on the scale that indicates how you feel about each of the statements right now.

1. Do you feel any study product effects?
2. Do you feel any good study product effects?
3. Do you feel any bad study product effects?
4. How much do you like the study product?
5. How much do you desire the study product?
6. How much would you like to use this product again?



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HEDONIC ATTRIBUTE PROFILE

Draw	1 TOO EASY	2	3	4 JUST RIGHT	5	6	7 TOO HARD
Mouthful of Smoke	1 TOO LITTLE	2	3	4 JUST RIGHT	5	6	7 TOO MUCH
Impact	1 TOO LITTLE	2	3	4 JUST RIGHT	5	6	7 TOO MUCH
Irritation	1 TOO LITTLE	2	3	4 JUST RIGHT	5	6	7 TOO MUCH
Strength	1 TOO MILD	2	3	4 JUST RIGHT	5	6	7 TOO STRONG
Smoothness	1 TOO SMOOTH	2	3	4 JUST RIGHT	5	6	7 TOO HARSH
Tobacco Taste	1 TOO LITTLE	2	3	4 JUST RIGHT	5	6	7 TOO MUCH
Tobacco Taste	1 UNPLEASANT	2	3	4 NEUTRAL	5	6	7 PLEASANT
Overall Taste	1 UNPLEASANT	2	3	4 NEUTRAL	5	6	7 PLEASANT
Aftertaste	1 UNPLEASANT	2	3	4 NEUTRAL	5	6	7 PLEASANT
Similarity to Usual brand	1 VERY DIFFERENT	2	3	4	5	6	7 VERY SIMILAR

PANAS (10 item) [1-5 Not at all – Extremely]

The next part involves a number of words that describe different feelings and emotions. I'll say each word, and you can indicate to what extent you feel this way RIGHT NOW, on a scale from 1-5. 1 means you don't feel this way at all or slightly feel this way right now. 2 means feeling this way a little, 3 means moderately, 4 means quite a bit, and 5 means extremely feeling this way right now.

1. Inspired
2. Afraid
3. Alert
4. Upset
5. Excited
6. Nervous
7. Enthusiastic
8. Scared
9. Determined
10. Distressed

Questionnaire of Smoking Urges – BRIEF [1-7 Likert scale, Strongly disagree – strongly agree]

1. I have a desire for a cigarette right now.
2. Nothing would be better than smoking a cigarette right now.
3. If it were possible, I probably would smoke right now.
4. I could control things better right now if I could smoke.
5. All I want right now is a cigarette.
6. I have an urge for a cigarette.
7. A cigarette would taste good now.
8. I would do almost anything for a cigarette now.
9. Smoking would make me less depressed.
10. I am going to smoke as soon as possible.

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CONTEMPLATION LADDER

Each rung on this ladder represents where various smokers are in their thinking about quitting. Place an X on the mark that indicates where you are now.

Taking action to quit (cutting down, enrolling in a program)

Starting to think about how to change my smoking patterns

Think I should quit but not quite ready

Think I need to consider quitting someday

No thought about quitting

Ladder 1 Score

☐☐

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Health Risk Ladder

Please tell me where you would put these cigarettes on the health risk ladder.

Very high risk of lung or heart disease

Very low risk of lung or heart disease

Ladder 1 Score

☐☐

ANTICIPATED RESPONSES

Health authorities may, in the future, require manufacturers to change their cigarettes in certain ways. These changes could make cigarettes taste differently.

If the taste of your cigarettes became more harsh or unpleasant, what do you think you would be MOST likely to do.

☐I would quit smoking entirely
☐I would switch to vaping/using e-cigarettes
☐I would switch to smokeless tobacco
☐I would find a way to get cigarettes that were similar to my old ones
☐I would continue smoking the new version
☐Don't know

If the taste of your cigarettes became more harsh or unpleasant, what do you think you would be LEAST likely to do.

☐I would quit smoking entirely
☐I would switch to vaping/using e-cigarettes
☐I would switch to smokeless tobacco
☐I would find a way to get cigarettes that were similar to my old ones
☐I would continue smoking the new version
☐Don't know

Kessler-6 (Serious psychological distress)

The following questions ask about how you have been feeling during the past 30 days. For each question, please indicate the answer that best describes how often you had this feeling.

1. During the past 30 days, about how often did you feel...

1.a. ...nervous?
1 [ ] All of the time
2 [ ] Most of the time
3 [ ] Some of the time
4 [ ] A little of the time
5 [ ] None of the time

1.b. ...hopeless ?
1 [ ] All of the time
2 [ ] Most of the time
3 [ ] Some of the time
4 [ ] A little of the time
5 [ ] None of the time

1.c. ... restless or fidgety?
1 [ ] All of the time
2 [ ] Most of the time
3 [ ] Some of the time
4 [ ] A little of the time
5 [ ] None of the time

1.d. ...so depressed that nothing could cheer you up?
1 [ ] All of the time
2 [ ] Most of the time
3 [ ] Some of the time
4 [ ] A little of the time
5 [ ] None of the time

1.e. ...that everything was an effort?
1 [ ] All of the time
2 [ ] Most of the time
3 [ ] Some of the time
4 [ ] A little of the time
5 [ ] None of the time

1.f. ...worthless?
1 [ ] All of the time
2 [ ] Most of the time
3 [ ] Some of the time

4 [ ] A little of the time
5 [ ] None of the time

2. The last six questions asked about feelings that might have occurred during the past 30 days. Taking them altogether, did these feelings occur More often in the past 30 days than is usual for you, about the same as usual, or less often than usual? (If you never have any of these feelings, circle response option "4.")

1 [ ] A lot (More often than usual)
2 [ ] Some (More often than usual)
3 [ ] A little (More often than usual)
4 [ ] About the same as usual
5 [ ] A little (Less often than usual)
6 [ ] Some (Less often than usual)
7 [ ] A lot (Less often than usual)

The next few questions are about how these feelings may have affected you in the past 30 days. You need not answer these questions if you answered "None of the time" to all of the six questions about your feelings.

3. During the past 30 days, how many days out of 30 were you totally unable to work or carry out your normal activities because of these feelings?

_____ (Number of days)

4. Not counting the days you reported in response to 3, how many days in the past 30 were you able to do only half or less of what you would normally have been able to do, because of these feelings?

_____ (Number of days)

5. During the past 30 days, how many times did you see a doctor or other health professional about these feelings?

_____ (Number of times)

6. During the past 30 days, how often have physical health problems been the main cause of these feelings?
1 [ ] All of the time
2 [ ] Most of the time
3 [ ] Some of the time
4 [ ] A little of the time
5 [ ] None of the time

Home environment

1. Do you have any children living in your home? Yes, No

If yes, How many? Ages?

Smoke Free home and vehicle policies

These next few questions ask about rules of using tobacco inside your home. Please think about everyone who might be in your home including children, adults, visitors, guests, or workers. For tobacco products that are burned, such as cigarettes, cigars, pipes, or hookah, which statement best describes the rules about smoking a tobacco product inside your home?

1 It is not allowed anywhere or at any time inside my home

2 It is allowed in some places or at some times inside my home

3 It is allowed anywhere and at any time inside my home

-8 DON'T KNOW

-7 REFUSED

Do you have a car (this includes a car, van, suv, or any other enclosed vehicle)?

IF YES: For tobacco products that are burned, such as cigarettes, cigars, pipes or hookah, which statement best describes the rules about smoking a tobacco product inside your car?

1 It is not allowed anywhere or at any time inside my car

2 It is allowed in some places or at sometimes inside my car

3 It is allowed anywhere and at any time inside my car

-8 DON'T KNOW

-7 REFUSED

Vape-free home and vehicle policies

For electronic cigarette products, such as e-cigarettes, vape pens, tanks, mods, JUUL, which statement best describes the rules about vaping inside your home?

1 It is not allowed anywhere or at any time inside my home

2 It is allowed in some places or at sometimes inside my home

3 It is allowed anywhere and at any time inside my home

-8 DON'T KNOW

-7 REFUSED

IF CAR=YES: For electronic cigarette products, such as e-cigarettes, vape pens, tanks, mods, JUUL, which statement best describes the rules about vaping inside your car?

1 It is not allowed anywhere or at any time inside my car

2 It is allowed in some places or at some times inside my car

3 It is allowed anywhere and at any time inside my car

-8 DON'T KNOW

-7 REFUSED

Responses to pack messaging

In your opinion, how would you rate the label you just saw on each of the following characteristics
1='Not at all' to 10='Extremely'.

Effective in discouraging smoking in youth
Effective in encouraging smokers to quit
Believable information
Truthful information
Exaggerated information
New information
Hard to understand
Applies to me

Message Perceptions
This message is:
Worth remembering
Grabs attention
Powerful
Informative
Meaningful
Convincing

Effect Perceptions
This message:
Discourages me wanting to smoke
Makes smoking seem unpleasant to me
Makes me concerned about health effects of smoking

Negative Affect
How much did the label make you feel:
Anxious
Sad
Scared
Guilty
Disgusted

Thinking of Harms
How much did the labels make you think about:
The chemicals in the smoke of the cigarettes
Health problems caused by smoking
The harm your smoking might be doing to you
The harm your smoking might be doing to other people

Would you support or oppose a policy that required this label to appear on cigarette packages?
Strongly oppose – Strongly support

Would you support or oppose a policy that required this label to appear in advertising for cigarettes?
Strongly oppose – Strongly support

Remote Data Collection – EMA Schedule and Questionnaires
3 Daily Reports – 11 am, 4pm, 9pm (assessments < 5min)

How many cigarettes have you smoked since the last prompt?
How many of these cigarettes were research cigarettes?
How many of these cigarettes were not research cigarettes?
How you used any other tobacco products since the last prompt?
If yes: What product? How many times did you use it?
Please record your product weight with the provided scale.

RIGHT NOW: How would you rate your (0 – 100 VAS):

- Craving
- Irritability
- Anxiousness/nervousness
- Difficulty Concentrating
- Stress
- Bored
- Calm/Relaxed
- Happy
- Alert
- Enthusiastic

Provide Reminder to collect all cigarette butts in provided materials, store used pods

11 am Only (additional questions)

Hedonic Attribute Profile: In the past day, how would you rate the research cigarettes (1-7 Likert)
Draw
Irritation
Smoothness

Strength
Tobacco Taste
Similarity to Usual Brand

Product Evaluation Scale (1 -7 Likert):

Was it satisfying?
Did it taste good?
Did it calm you down?
Did you enjoy the sensations in your mouth?
Did it reduce your craving for a cigarette?
Were there bothersome side effects?
Did you enjoy using the product?
Would you be willing to use the product long term?

Record CO measurement

9pm Only (additional questions):

Record CO measurement

Reflect on today as a whole: How would you rate your (0 – 100 VAS)

- Craving
- Irritability
- Anxiousness/nervousness
- Difficulty Concentrating
- Stress
- Bored
- Calm/Relaxed
- Happy
- Alert
- Enthusiastic

Thinking of the cigarettes you smoked today: How would you rate (0 – 100 VAS)

- Tastes like my own brand
- Satisfying like my own brand
- Enjoyable like my own brand
- Relieved my cravings like my own brand

2-3 Pseudo-Random Prompts: Between 11 - 4, 4 – 9

Take picture of research cigarette pack

How often did you notice your warning label in the past day?

Have you read or looked closely at the warning label in the past day?

Have you made any effort to avoid looking at or thinking about the warning labels (such as covering them up, keeping them out of site, using a cigarette case, etc.)

Has seeing the warning label stopped you from having a cigarette when you were about to smoke?

Has seeing the warning label affected how you smoke a cigarette?

Has seeing the warning label affected how you hold a cigarette?

Think back on the most recent cigarette you smoked:

Where were you (home, work, other's home, vehicle, bar/restaurant outside, other)

Was smoking permitted (yes, discouraged, no)

Were you with others (yes, no)

- IF YES: Were they: smoking, vaping, both, neither

What activity were you doing (working/chores, inactive/leisure, socializing, eating/drinking, other)

How strong was your craving prior to use?

How many puffs did you take?

Duke Sensory Evaluation (1 – 7 Not at all – Extremely)

- How much did you like the puffs you took?
- How satisfying were the puffs you took?
- How high in nicotine do you think the puffs were?
- How similar to your own brand were the puffs?

Appendix D: Experimenter Guide

1. **Welcome and Introductions:**

2. Introduction:

- I would appreciate if you can minimize distractions until our videoconference is done. If something important requires your attention, please let me know and we can take a brief pause.
- First, I'll ask you to complete an online questionnaire. Here, we are looking for some information about you and your tobacco use.
- We will then move onto training you on study procedures.
- There is no right or wrong answer here. You are the expert and we are really interested in your honest responses to questions and to the tasks during the laboratory session.
- Do you have any questions?

*Answer any questions.

3. Baseline Questionnaires

- "We will now begin the baseline questionnaires."
    - Baseline measures and covariates will assess:
      - Demographics (age, sex, race/ethnicity, education, income)
      - Tobacco use behaviors (consumption, brand, menthol preference, quit history)
      - Cognitive and affective measures
    - A series of previously used items will assess knowledge and perceptions of filter vents.[113,117]
    - Nicotine dependence will be assessed using:
      - Fagerström Test for Nicotine Dependence (FTND;[118])
    - Behavioral aspects of cigarette dependence will be assessed using:
      - The Glover-Nilsson scale [120,121]
    - Questionnaires on vent messages
    - Questionnaires on message perceptions

We will now train you and provide you with supplies for the field study

Field Study Description

For the field study, you are going to use your mobile device to record your cigarette and other tobacco use and answer questions about how you're feeling and the situations in which you use your products. You will be prompted 5 times each day via text message to answer questionnaires. Three of these prompts will be at the same time every day: 11am, 4pm, and 9pm. Two of these prompts will be at a random time each day, one between 11am – 4pm and one between 4pm – 9pm. To receive bonus payment for the field study, you will need to respond to

all 5 prompts. If you fail to respond to prompts for 3 consecutive days, we will send you a warning. If compliance to procedures does not improve, you will be discontinued from the study.

Please keep track of the amount of cigarettes and other tobacco you use. The scheduled prompts will ask you to report the number of cigarettes you've smoked. The random prompts will ask you to report on the situation in which you last used your product, such as the location and if smoking was allowed. We also ask that you store all used cigarette butts in the provided materials

Here are examples of the questions you will be asked at each assessment (show questionnaires). Do you have any questions?

We are also providing you with a CO monitor that will connect with your phone to take a CO measurement each night (demonstrate use).

We are also providing you with a scale to weigh other tobacco products that you may use, such as an e-cigarette or smokeless tobacco. If you use these other products, we would like you to weigh your product (e.g., pod, tank, dip tin) at the beginning and end of each day. If you are close to finishing your product and may start a new one, please weigh both the older and newer one at the beginning and end of the day.

Two additional times during the field study, we will ask you to videoconference with us as a study check-in and to have you respond to some questionnaires.

These are the cigarettes we are asking you to use during the field study (provide research cigarettes). Please use only these cigarettes and do not tamper with the cigarette pack. At random points in the study, we may ask you to take a picture of the cigarette pack.

Do you understand the procedures for the field study? Please call us if you have any questions.

Videoconferencing Sessions 2 & 3

Hello, today we are going to have you fill out a questionnaire. I will send it to you now.
Have you been regularly storing your cigarette butts. Can I see how you are storing them?

Compliance: Your compliance has been great. Thank you!
Or: Your compliance has not met the standards. Please respond to more prompts or you may be discontinued for the study. Do you have any questions about the study procedures that may help you respond to more prompts?

Session 3 only:
Please pack up your supplies to prepare a return shipment. Can I see how you've stored your supplies in the box?

When we receive your materials, we will send you payment for completing the study. Thank you for participating.

Roswell Park Protocol Number: I 757820

Ads for the website/mobile app: