Evaluation of the new FDA warning labels: Does highlighting lesser known harms of tobacco use increase attention, recall and knowledge of tobacco harms compared to well-known harms?

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1 Study Summary

Title	PILOT: Evaluation of the new FDA warning labels: Does highlighting lesser known harms of tobacco use increase attention, recall and knowledge of tobacco harms compared to well-known harms?
Short Title	FDA Labels: Eye Tracking Study
IRB Number	**843703**
Methodology	This laboratory-based study will aim to enroll 70 current cigarette users to complete a 1-day cross-sectional, randomized, parallel design protocol. The participants will be randomized to one of two conditions, pictorial warning labels (PWLs) with well-known versus lesser-known tobacco harms. After completing a baseline questionnaire, the participants will view about 4 labels from the assigned group and complete a follow-up questionnaire. Eye-tracking equipment will provide data on visual processing of the warning labels and the effect of these labels on knowledge, attitudes and beliefs about smoking will be supplemented by self-report.
Study Center(s)	Single-center
Objectives	**Aim 1**: To assess daily smokers' response to FDA PWL content on visual engagement, recall and knowledge **Aim 2:** To conduct a laboratory-based study to evaluate effects of PWL risk content (lesser-known vs well-known risks) on visual engagement, recall and knowledge
Number of Participants	70 participants (randomized)

Main Inclusion and Exclusion Criteria	Main Inclusion: 1. Current cigarette smokers who smoke at least 5 cigarettes per day who are between 21 and 65 years of age. Participants must physically present a pack of their preferred brand of cigarettes during the session to confirm their status as a regular cigarette smoker. 2. Not currently undergoing smoking cessation treatment or planning to quit smoking. Main Exclusion: 1. Use of any nicotine-containing products other than cigarettes. Participants reporting isolated use of other nicotine containing products less than 5 times per month are eligible to participate. 2. Current or impending enrollment in a smoking cessation program. Further, participants will be excluded for an attempt to quit smoking over the duration of the study period. 3. Lifetime history or current diagnosis of COPD, cardiovascular disease, or heart attack. **The complete list of study inclusion and exclusion criteria is included within the Characteristics of the Study Population section of this protocol.**

2 Introduction

2.1 Background

The Food and Drug Administration (FDA), while implementing a provision of the Family Smoking Prevention and Tobacco Control Act (TCA), issued new cigarette health warnings for cigarette packages on August 15, 2019 (84 FR 42754). Pictorial warning labels (PWLs) are an effective way to communicate health risks of tobacco use [1] and research evidence from many countries shows a significant increase in awareness of smoking harms as a result of PWL exposure [2]. Multiple research studies have emphasized the effectiveness of pictorial warning labels compared to text-only warnings for increasing knowledge regarding smoking risks, likelihood to reduce cigarette demand and promoting quitting [3–6]. Despite the general assumption that smokers are aware of risks associated with smoking, even in high income countries such as United States and Canada – significant gaps in health knowledge remain [7]. The newly released warning labels include lesser-known harms of smoking such as macular degeneration, bladder cancer and erectile dysfunction. Currently, there is limited evidence on the effect of lesser-known harm warnings on attention, recall and knowledge increase of tobacco related harms.

This study, as a part of Pilot Project of the Tobacco Centers of Regulatory Science (TCORS), will examine the effect of the newly proposed FDA PWLs on daily smokers on visual engagement, knowledge, and recall.

It is as an exploratory experimental study using objective measures and self-report survey. We will recruit 70 daily smokers to participate in a single-session laboratory-based study. The participants will be assigned to either the lesser-known harm group or well-known harm group of PWLs. They will first view 4 warning labels in a randomized order from the assigned group following which they will view all 11 warnings and rank them based on avoidance, preference and being most informative. Primary outcomes will be eye-tracking measures, correct recall of text, image and message, knowledge of tobacco harms and risk-perceptions.

This document is a human research protocol for a TCORS Pilot Study. This study will be conducted in compliance with this research protocol and according to U.S. standards of Good Clinical Practice (GCP), applicable government regulations, and institutional research policies and procedures.

2.2 Rationale

2.2.1) Rationale for between subject condition – warning labels

The new warning labels are created in compliance with court recommendations and tailored to increase knowledge of smoking harms. 6 out of 11 warning labels highlight lesser-known smoking harms. The participants will be randomized to one of two conditions – one containing FDA warning labels bearing lesser known and another with better-known tobacco use risks. In Canada, packages include information about smoking causing impotence and therefore, twice as many respondents reported impotence as tobacco harm relative to respondents in US, UK and Australia[7]. There have been no previous studies that have evaluated the impact of highlighting lesser known harms of tobacco; they are now a part of FDA's label policy and would add to the literature on tobacco control messaging.

2.2.2) Rationale for primary outcome measures

Previous PWL studies using eye-tracking methodology have used latency, latency duration and total dwell time[11–13] to characterize visual engagement and this study will continue to use these measures for consistency and comparisons. The image/text/message recall and knowledge measures are a good indicator of information retention and effectiveness of the labels.

3 Study Objectives

Aim 1: To assess daily smokers' response to FDA PWL content on visual engagement, recall and knowledge.

H1a: Warning label images may have greater visual engagement when compared to text portions of the PWLs

H2a: The recall for image areas of PWLs might be higher post-exposure in comparison to text areas of interest.

Aim 2: To evaluate effects of PWL risk content (lesser-known vs well-known risks) on visual engagement, recall and knowledge

H2a: Warning labels bearing images of lesser known tobacco use harms will have longer latency and fixation durations than warning labels bearing images of well-known harms of tobacco.
H2b: The initial image/text/gist recall of PWL text and message with lesser known harms may be lower than well-known harms.
H2c: The knowledge increase will be greater among smokers exposed to warning labels highlighting lesser known harms of tobacco.

Secondary Aims:

To examine the perceived effectiveness of all the warning labels. A personalized effectiveness ranking[11] for each participant will be collected by asking them to rank their top 3 warning labels on being most avoidant, preferred and informative.

4 Study Design

4.1 Design

Study participants will be randomized to view one set of graphic warning labels with either lesser-known or well-known harms of tobacco use. The labels will be presented on a computer screen while their eye movements are recorded for each label seen. Participants will provide smoking and quitting related attitude, belief and intention measures and answer questionnaires before and after viewing the labels during the in-person session. This laboratory-based study will aim to enroll 70 current cigarette users to complete a 1-day, randomized, parallel design protocol. We base this design on our previous and ongoing studies using eye-tracking methodology.

4.2 Study Duration

Recruitment/enrollment is anticipated to begin in November 2020. We estimate that up to 70 participants will be randomized and complete the study within a year. Each participant will attend the single, 2-hour study session.

5 Characteristics of the Study Population

5.1 Target Population

Participants will include 70 daily smokers aged 21-65 who report currently smoking cigarettes and have been smoking at least 5 cigarettes daily for at least the last year.

5.2 Accrual

We have ongoing projects with current smokers who meet the criteria for the study. At the conclusion of those studies, we ask participants if we can contact them regarding future research opportunities. Further, we will post flyers and advertise online, similar to our previous recruiting efforts. We will enroll (i.e., sign an IRB-approved informed consent form) ~70 participants to . To achieve this goal, we intend to recruit 5-7 participants per month, which will allow us to enroll and randomize enough participants to complete data collection as proposed. The sample size was determined based on a previous graphic warning label eye-tracking study by Mercincavage et al.[11]

and Lochbuehler et al.[12] which was sufficiently powered to detect effects of a content attribute (congruency) on eye-tracking measures and image/text/message recall. In order to maximize participation in the study we will: (1) educate participants about the benefits of participation and the knowledge gained from the study; (2) schedule sessions at times convenient for participants; (3) provide reminder calls, emails, and potentially texts; and (4) provide payment for completion of the study visit and study requirements.

5.3 Key Inclusion Criteria

1. Current cigarette smokers using only filtered commercially manufactured cigarettes; smoking at least 5 cigarettes daily and smoking for at least last 1 year.
2. Age greater than 21 years and less than or equal to 65 years.
3. Participants must physically present a pack of their preferred brand of cigarettes at the lab session to confirm their status as a cigarette smoker.
4. Not currently undergoing smoking cessation treatment or planning to quit smoking currently or in the next month.
5. Plan to live in the area for the duration of the study.
6. Capable of giving written informed consent, which includes compliance with the requirements and restrictions listed in the combined Informed Consent and HIPAA form.
7. Able to communicate fluently in English (i.e., speaking, writing, and reading) as determined by the research assistant.
8. Male, female, non-binary or other.

5.4 Key Exclusion Criteria

Participants who do not meet the inclusion criteria or present and/or self-report with the following criteria will not be eligible to participate in the study. After final eligibility is confirmed, participants who present and/or self-report with any of the following exclusions during the study period may only remain eligible after the case is reviewed by Principal Investigator and it is determined that the situation does not significantly impact the study design, data quality, and/or participant safety and welfare.

- Use of any nicotine-containing products other than cigarettes. Participants reporting isolated use of other nicotine containing products less than 5 times per month are eligible to participate.
- Not actively trying to quit smoking currently and had not made a quit attempt in the past month.
- Self-report current alcohol consumption that exceeds 25 standard drinks/week.
- Self-report current pregnancy or breast feeding.
- Any self-reported impairment - visual (colorblindness or impairments such as glass eye), physical, and/or neurological impairments preventing the proper completion of the study procedures.
- Serious or unstable medical condition.
- Lifetime history of schizophrenia, psychosis, and/or bipolar disorder.
- Current use or discontinuation of anti-psychotic medications within the last 6 months.
- Current diagnosis of active major depression. Participants who maintain a diagnosis of major depression who have not experienced any major depressive episodes in the past 6 months and are stable on antidepressant medication(s) are eligible to participate.

- Inability to provide informed consent or complete any of the study tasks as determined by the principal investigator.

5.5 Vulnerable Populations

Children, pregnant women, fetuses, neonates, or prisoners are not included in this research study. Educationally or economically disadvantaged persons are included but not solely targeted for recruitment. Because of our recruitment efforts for this study, it is possible that University of Pennsylvania employees and students may be invited to participate. Status of participation in the current study will be independent of the participant's work or school activities.

5.6 Participant Recruitment

Anupreet Sidhu will oversee the study recruitment. Participants may be recruited from television, radio, internet advertisements, newspaper, flyers, transit posters, referrals, and/or from our database of previous participants who have agreed to be re-contacted for future studies. Interested participants will first complete an online RedCap screener or a telephone screen to assess their initial eligibility. Participants who are initially eligible will be screened against our registration database to confirm that they are not currently participating in another research study at our Center and have not previously reported a condition or circumstance that would make them ineligible for the current study. Those participants who remain initially eligible will then be invited to attend the lab session at our Center during which they will be presented with the IRB-approved Informed Consent Form and have their final eligibility confirmed.

Study Procedures

5.7 Eligibility Screen

The initial pre-screening and eligibility screening will be completed via RedCap surveys. The link to RedCap survey will be shared in the recruitment materials and will be provided to any participants from previous studies who might be eligible for this study. In cases where a participant does not have access to the online screener, initial eligibility will be determined during a structured Telephone Eligibility Screen conducted by a trained member of the research team. If a participant is found to be initially eligible per the applicable inclusion and exclusion criteria, the lab session will be scheduled in order to confirm the participant's final eligibility and to complete the study questionnaires and viewing tasks. A completed telephone screen will take approximately 30 minutes.

5.8 Procedures

The lab session will occur at the Center for Interdisciplinary Research on Nicotine Addiction (CIRNA). Participants will typically receive a session reminder 24 – 48 hours prior to their scheduled session via phone call, email, and text message (if applicable).

During the session (Duration: ~2 hours), participants will complete the following:

1. Confirm the accuracy of information (i.e., name, address, phone number, email [if applicable], date of birth, age, ethnicity, race, sex assigned at birth, gender, cigarette brand type) provided during the initial Telephone Eligibility Screen. Participants will be explicitly instructed to bring in their own preferred brand of cigarettes to verify their preferred brand. If the participant does not bring in the brand of cigarettes, they reported during the Telephone Eligibility Screen, the participant may be deemed ineligible or their session may be rescheduled to a later time/day.
2. Receive and review a research study summary for potential participants. If the participant is still interested in participating in the study, they will be presented with the complete combined Informed Consent Form per below.
3. Be presented with the combined Informed Consent Form. The Informed Consent Form will be read to the participant verbatim. All of the participant's questions will be answered. Both the questions and subsequent answers will be recorded on an "ICF/HIPAA Questions Form," which will be maintained with the original Informed Consent Form. If the participant agrees to participate in the study, the Informed Consent Form will be signed (legal name) and dated by both the participant and a qualified member of the research team. Participants will receive a signed copy of the Informed Consent Form for their records.
4. Smoke a cigarette (own brand) outdoors to standardize the time to last smoke.
5. Complete baseline questionnaire:

- Cigarette Brand Form - While viewing the participant's cigarette pack, the research staff will record the cigarette brand information on the form as appropriate. Additionally, a photocopy of the participant's cigarette packaging will be obtained for further verification of preferred brand and flavor.
- Demographics and Sexual Orientation
- Smoking History
- Nicotine Dependence (FTND)
- Pre-test measures of smoking related beliefs, attitudes towards quitting and knowledge of tobacco harms.
- No CO measurements will be collected during the session to minimize the risk of COVID-19 infection.

6. Participants will then have their eye tracking session, completing a calibration task followed by exposure to their assigned graphic warning labels. Participants will then complete a recall task and a questionnaire with knowledge, risk beliefs and attitude measurement.
7. After viewing labels from their assigned group, each participant will perform a recognition and ranking task for all 11 labels proposed for cigarette packs by the FDA.
8. Participants will be provided compensation for their participation.

5.9 Description of Study Measures

5.9.1 Screening and Covariates

Age, Date of Birth (DOB), Sex Assigned at Birth, Gender, Ethnicity, and Race: Participants will report their Age, DOB, Sex Assigned at Birth, Gender, Ethnicity, and Race during the initial telephone eligibility screen. During the study session, the previously reported information will be verified in person with the participant by the research staff.

Cigarette Use Survey and Brand Form: Participants will complete a standardized survey about their cigarette use (i.e., pack type, brand, filtered or non-filtered, flavor, menthol or non-menthol, frequency, and additional information). In addition, a photocopy of the participant's cigarette pack will be obtained for further verification of brand and flavor.

Demographics, Smoking History, and Nicotine Dependence (FTND): Standard questionnaires will be administered to collect the following data: demographics, age at smoking initiation, current smoking rate, and intentions to quit. The Fagerstrom Test for Nicotine Dependence (FTND) will also be administered. The FTND is a 6-item, self-report measure of nicotine dependence derived from the Fagerstrom Tolerance Questionnaire.

5.9.2 Eye tracking, Recall and Knowledge (Primary Outcomes)

Eye tracking: Participants will view the warning labels on a computer screen while wearing an eye movement tracker. The eye tracking device will provide key measure such as latency, latency duration and fixation duration for text as well as image areas of interest.

Recall: The participants will provide answers to an open-ended recall question for the text, image and/or overall message question. For the recognition task, the participants will also view all 11 label images and text statements, and would be required to identify the warning labels and text statements they saw earlier.

Knowledge: All participants will select harms caused by tobacco from a list of health issues and diseases, before as well as after viewing the warning labels on screen.

5.9.3 Secondary Measures

Perceived Effectiveness Warning Label Ratings: Participants will provide subjective ratings of all the warning labels released by the FDA on measures of most and least avoidant, believable and informative.

5.10 Analytic Plan

Descriptive statistics will be used to characterize the study population and smoking-related data. A factorial design will be used. The primary independent variable is warning label type (lesser-known harms vs well-known harms. Associations of independent and covariate variables with eye-tracking measures, recall, and knowledge will be assessed using unpaired t-tests or ANOVA (categorical predictors) and linear regression analysis (continuous predictors). Eye-tracking measures are continuous, and previously been observed to meet assumptions of normality. Recall is dichotomous and will be examined using logistic regression model to generate odds ratio, as in our previous work (Strasser et al., 2012; 2008). A primary outcome measure of this study is change in knowledge after exposure to graphic cigarette warning labels. This measure will be continuous when calculated on a scale and categorical when coded as increase in knowledge vs no change. Chi-square and regression analysis can be used to assess association of knowledge change with label type and by age group. Analysis will be conducted in a using Stata (Stata Corp., TX). Path analysis techniques for tobacco related mediation and moderation models will be used; covariates found to be significantly associated will be considered for inclusion in models as appropriate.

6 Risk / Benefit Assessment

Although cigarette smoking is associated with many diseases, we do not anticipate that any risk of smoking 1 cigarette during a study session is beyond the everyday risk to all participants who need to be smoking at least 5 cigarettes daily to be eligible for the study. The anticipated benefit of this study, in general, is to evaluate the effectiveness of graphic warning labels. Results from this study may then be used to guide FDA regulation of the images used on cigarette packs. Others will be able to potentially benefit from this study by having improved tobacco policy put into effect that will reduce the impact of cigarette smoking on the US population.

The potential benefits of this study outweigh the potential risks. There is only a minimal risk of experiencing study-related AEs or SAEs by enrolling in this trial. In addition, we will minimize any risks related to loss of privacy by maintaining strict confidentiality. Results from this trial, however, may have scientific and policy implications by providing empirical support for FDA policy on cigarette packaging regulation in tobacco products and educating smokers on the risks of smoking.

7 Data Management

The CIRNA Data Management Team has developed a data management system (DMS) that will facilitate the operational facets of this study, including collection, validation and storage of participant data, tracking recruitment call attempts, participant study milestones, accrual goals, and exporting data for use in statistical analysis and data sharing. The DMS integrates Microsoft Access, REDCap and AutoData Scannable Office.

REDCap (Research Electronic Data Capture) is the primary software platform for collecting and storing questionnaire data. REDCap is a web-based application developed by Vanderbilt University to capture data for clinical research. It is HIPAA-compliant, and highly secure. REDCap ensures data integrity through range and validity checks during the data entry process.

In addition to REDCap, some data may be collected using scannable forms created in AutoData Scannable Office. Scannable Office uses Microsoft Word to create forms that are mapped to a MS Access database and processed with an imaging scanner. During the scanning process, response data is captured and written directly into the database. Microsoft Access is a relational database product and the primary software platform for project management. The MS Access databases contain VBA programming to automate report generation (e.g., accrual, enrollment, AE tracking, participant compliance, and recruitment sources), calculate study milestone dates, performing range/validity checks as users enter data, generate custom error messages to control user input, and populate information displayed on participant study materials.

7.1 Data Management System Development

The CIRNA Data Manager will work closely with the trial investigators to develop an understanding of the data collection, storage, and quality assessment needs for the trial. This includes the design and development of the trial data collection forms and REDCap surveys. The data collection forms will serve as templates for designing the data entry screens. The Data Manager will work closely with the investigators to design, develop, and test an appropriate database structure to support the requirements of the DMS and to promote data security and integrity. Electronic audit trails of changes to database contents (including REDCap) are incorporated into the design and will capture and record those changes automatically.

7.2 Data Security

Data collected in an Access database and REDCap will be stored on a secure server administered by the Penn Medicine Academic Computing Services (PMACS) organization and will be restricted to only those individuals who are authorized to work on the trial. Individual user accounts with passwords will be used to restrict access to the database. Specific privilege assignments within the database will also be employed to limit the types of functions that authorized users can perform to those functions that are appropriate for their role in the trial. Additional measures to prevent unauthorized external access to the database environment will be employed using network firewall technologies. The Data Manager will maintain the database in an appropriate manner for the retention period required by regulation. Database administration includes user account maintenance, database security, performance monitoring, and database change management. Daily backups are performed to protect data against accidental destruction or corruption.

7.3 Data Processing

The data entry screens will resemble the data collection forms as closely as possible to allow visual referencing during data entry. The data entry module will be configured for single data entry. The majority of participant data will be self-report and participants will either enter data into Qualtrics using computer, tablets or complete paper-and-pen forms during in-person visits. Some data might be collected by research staff, recorded on study-specific source documents/CRFs, and scanned in or entered directly into REDCap or MS Access. Data entry checks will be included in the entry screen designs, where appropriate, to limit the opportunity for erroneous entries due to mistyping. Such data entry checks would include value range comparisons, valid data type checks, required value checks, and/or skip pattern enforcement. Following initial telephone eligibility screening, research staff will perform subject registration.

Prior to lab session, research staff will randomize eligible participants. The randomization module will allow the research staff to randomize participants into one of the two trial arms. At the randomization attempt, the DMS will confirm milestones are accurate and that the randomization is valid. A randomization assignment will then be provided.

8 Data and Safety Monitoring

8.1 Research Roles

During the study, data and safety monitoring will be performed on an ongoing basis by the Principal Investigator, research staff, and the Penn IRB. The research staff are responsible for collecting and recording all data. Research staff will meet and communicate on a regular basis to reconcile data queries and safety concerns.

8.2 Staff Training

Staff training will consist of an initial explanation and review of the protocol, combined Informed Consent Form, source documents/REDCap/Qualtrics surveys, sample collection protocols, data management system, AE collection and reporting, and all study-specific SOPs, which will be maintained in an accessible electronic manual of procedures. In addition, during a standardized training period, the duties of each staff member will be clearly outlined, and all applicable regulations will be reviewed by senior staff and the Principal Investigator. All personnel working on this project will complete required training in the protection of human participants and the protection of PHI (i.e., HIPAA) before interacting with study data or research participants. All human participant and privacy protections certifications will be maintained in the regulatory binder.

8.3 Monitoring Activities

8.3.1 Initial Assessment (Lab Session) Monitoring

The study staff will conduct a manual quality assurance review of a participant's telephone screen documentation to confirm the participant's initial eligibility prior to their session. Further, eligibility data will be closely reviewed in real-time by the research staff.

8.3.2 Database Auditing

As outlined in the Data Management section, the study DMS and REDCap will be equipped with internal validation checks to ensure data is entered within reasonable ranges. Error messages will be displayed in real-time if data appears inaccurate. Staff will have to respond to these error messages before data can be saved. In addition, the Project Manager (or senior personnel) will perform regular milestone quality assurance checks.

8.3.3 Data Security

As outlined in the Data Management section, study data will be secured through controlled user access on networked computers and tablets with password-protected access.

8.4 Frequency of Data and Safety Monitoring

Data will be reviewed internally on a regular basis. Specifically:

1. At data capture, the research staff will review data for completeness and integrity. Further, REDCap will include multiple internal validity checks which will prompt the staff if an entry was made that is out of range or in an unacceptable format
2. At data entry, the DMS will include multiple internal validity checks which will prompt the staff if an entry was made that is out of range or in an unacceptable format.
3. Eligibility data will be reviewed by the research staff in real-time during the session.
4. The Investigators will review data prior to analysis to ensure integrity and validity.
5. Any adverse event will be reviewed and after removal of identification information, all AEs and SAEs will be reported to the UPenn IRB and the funding agencies within 24 hours.

9 Ethical Considerations

This study is to be conducted according to US and international standards of GCP, applicable government regulations, and Institutional research policies and procedures. This protocol and any amendments will be submitted to a properly constituted independent IRB, in agreement with local legal prescriptions, for formal approval of the study conduct. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator and a copy of this decision will be provided to the investigator before commencement of this study.

9.1 Informed Consent and HIPAA

Prospective participants will be informed about the study and interviewed for eligibility on the phone with a trained research assistant. After a participant is deemed eligible, the lab session will be scheduled within a month of completing the phone screen. A trained staff member will obtain informed consent using an Informed Consent Form approved by the Penn IRB. The consent process will take place prior to the initiation of any study procedures and will take place in English. The consent process will occur in person at the CIRNA and will involve a discussion of the study requirements and procedures. The Informed Consent Form will be read verbatim to participants. Participants will have an opportunity to ask any questions and/or express concerns that may have. Participants will receive a copy of the Informed Consent Form for their records. If the participant agrees to participate in the study, the Informed Consent Form must be signed (legal name) and dated by both the participant and the investigator-designated staff member obtaining the consent.

10 Resources Necessary for Human Research Protection

10.1 Research Staff

The following research personnel will be directly involved with the implementation and execution of the current study:

- Anupreet Sidhu, Ph.D., Principal Investigator
- Andrew Strasser, Ph.D., Co-Investigator
- Melissa Mercincavage, Ph.D., Co-Investigator
- Susan Ware, Database Developer and Data Manager
- Valentina Souprountchouk, Research Staff
- Catherine Kreider, Research Staff

- Emma Pitcher, Research Staff
- Amanda Lopez, Research Staff
- Lizza Waugh, Research Staff
- Kendra House, Research Staff
- Julia Villasenor, Research Staff
- Kiera Zehner, Research Staff
- Andrea Johnson, Ph.D., Research Staff
- Teresa DeAtley, Ph.D. Research Staff
- Matthew Stone, Ph.D. Research Staff

10.2 Study Facilities

This project will be conducted at and through the CIRNA. The CIRNA has successfully conducted similar protocols and has well-developed procedures for staff training, data collection and storage, and study completion. The facilities available for this project include a large and small conference room, ventilated smoking laboratories, storage rooms, office space for study personnel, and data management facilities.

11 Study Finances

11.1 Funding Source

This study is part of the Pilot Program within the UPENN Tobacco Centers of Regulatory Science center grant awarded by FDA, NIH and NCI.

11.2 Conflict of Interest

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by a properly constituted Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All University of Pennsylvania investigators will follow the University conflict of interest policy.

11.3 Participant Compensation

Participants will be compensated for the in-person visit with $50.00 in the form of a Greenphire Clincard, for successfully completing all of the study requirements. The “task completion” compensation will depend on the participant arriving on time for the scheduled session, responding to pretest questionnaire, completing the eye-tracking task, and completing posttest questionnaire. Participants not bringing in a pack of their preferred brand of cigarettes to the session as instructed will not be eligible to receive any compensation ($0). A detailed compensation breakdown will be reviewed during the informed consent presentation and throughout the course of the trial. Participants will be asked to complete a W-9 tax form at the conclusion of the session because the University of Pennsylvania is required to report to the Internal Revenue Service (IRS) any cumulative payments for participation in research studies at the University of Pennsylvania that exceed a total of $600.00 in a calendar year. A W-9 will aid

the Center in tracking and reporting those who participate in multiple projects at the Center and accrue over $600.00 in a calendar year.

Study Payment			
Session	**Visit & Task Compensation**	**Travel Reimbursement**	**Total**
1	$40.00	$10.00	$50.00
STUDY TOTAL			$50.00

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