Official Title of Study:
Effects of Cigarette and E-cigarette flavors on Substitutability in the Experimental Tobacco Marketplace (20-008)

ClinicalTrials.gov Identifier (NCT Number):
NCT06910202

Document Type:
Study Protocol

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Principal Investigator (PI):
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Sponsor/Collaborator:
Medical University of South Carolina

Confidentiality Statement:
This document does not contain names of research participants.

Institutional Review Board
Existing Data Research Protocol

Note: complete this application only if this research project ***only*** involves the collection or study of **existing data**. Once complete, upload this form as a Word document to the IRB Protocol Management System: https://secure.research.vt.edu/irb

1. DO ANY OF THE INVESTIGATORS OF THIS PROJECT HAVE A REPORTABLE CONFLICT OF INTEREST? (http://www.irb.vt.edu/pages/researchers.htm#conflict)

☒ **No**
☐ **Yes,** explain:

2. IS THIS RESEARCH SPONSORED OR SEEKING SPONSORED FUNDS?

☐ **No,** go to question 3
☒ **Yes,** answer questions within table

IF YES
Provide the name of the sponsor [if NIH, specify department]: National Institutes of Health, National Cancer Institute
Is this project receiving or seeking federal funds? ☐ No ☒ Yes **If yes,** **Does the grant application, OSP proposal, or "statement of work" related to this project include activities involving human subjects that are <u>not</u> covered within this IRB application?** ☐ No, all human subject activities are covered in this IRB application ☐ Yes, however these activities will be covered in future VT IRB applications, these activities include: ☒ Yes, however these activities have been covered in past VT IRB applications, the IRB number(s) are as follows: **20-008, 23-825, 21-1046, 17-896** ☐ Yes, however these activities have been or will be reviewed by another institution's IRB, the name of this institution is as follows: ☐ Other, explain: **Is Virginia Tech the primary awardee or the coordinating center of this grant?** ☒ No, provide the name of the primary institution: **Medical University of South Carolina - MUSC** ☐ Yes

3. DESCRIBE THE BACKGROUND, PURPOSE, AND ANTICIPATED FINDINGS OF THIS STUDY:

In 2009, the Food and Drug Administration banned all flavored conventional cigarettes except for menthol cigarettes. Although no such ban exists in the U.S. for E-cigarettes, such efforts have been proposed in several regions[1-3]. Flavors are possible objects of new tobacco control policy. Knowing whether flavors enhance or diminish substitution would be important in evaluating whether to support such bans on E-cigarette flavors. A report from the first wave of the PATH study of tobacco use found that 80% of youth, 73% of young adult and 29% of older adult smokers used flavored products[4]. They also report in that study that over 80% of young adults first used flavored tobacco products while the percentage was approximately 50% among adults. Lastly, the prevalence of current tobacco use among adult ever-users was 32% higher if the first tobacco product they used was flavored [4]. Importantly, one study asked flavored product users what they would do if the product they used was no longer flavored, and reported that 75% would no longer use the product [5]. Clearly, these data show the relevance of user type in understanding potential policies, but also raise the question of whether removal of flavors would result in greater quitting and intention to quit or lead to substitution with some other product.
Purpose: To examine the effects of e-cigarette and cigarette flavors availability on substitutability in the Experimental Tobacco Marketplace.
This study is designed to better understand the effect of possible restrictions in flavored tobacco products. We hypothesize that flavors availability and cigarette/e-cigarette price will affect substitution with other tobacco products differently across groups.

4. EXPLAIN WHAT THE RESEARCH TEAM PLANS TO DO WITH THE STUDY RESULTS:

For example - publish or use for dissertation

The research team plans to publish these results and findings in journals and present at conferences.

5. WILL PERSONALLY IDENTIFYING STUDY RESULTS OR DATA BE RELEASED TO ANYONE OUTSIDE OF THE RESEARCH TEAM?

For example – to the funding agency or outside data analyst, or participants identified in publications with individual consent

☒ **No**
☐ **Yes,** to whom will identifying data be released?

6. WILL THE RESEARCH TEAM COLLECT AND/OR BE PROVIDED PARTICIPANT IDENTIFYING INFORMATION (E.G., NAME, CONTACT INFORMATION, VIDEO/AUDIO RECORDINGS)?

☐ **No,** go to question 7
☒ **Yes,** answer questions within table

IF YES
Describe if/how the study will utilize study codes: **All participant data, including electronic data, will be stored in secure places to protect confidential participant information. Secured places will include locked filing cabinets, locked rooms accessible only to study personnel, and/or password-protected databases. Moreover, all data will be quality controlled in preparation for data analyses. All discrepancies in data entry will be checked against the raw data source, and the correct data entry will be used. All data entered into spreadsheets and databases will be coded by participant ID number and not by name (i.e., first and last name).**

If applicable, where will the key [i.e., linked code and identifying information document (for instance, John Doe = study ID 001)] **be stored and who will have access? All entered data will be backed up on secure password-protected servers. Computers used in the studies will also be password protected, accessible only by study personnel. IRB regulations will be strictly adhered to in the conduct of the proposed research. Specifically, prior to implementation of any protocol changes, amendments will be submitted to the IRB for approval.**

Note: the key should be stored separately from subjects' completed data documents and accessibility should be limited.

7. HOW WILL DATA BE STORED TO ENSURE SECURITY (E.G., PASSWORD PROTECTED COMPUTERS, ENCRYPTION) AND LIMITED ACCESS?

To secure study data computer databases will have coded identifiers, only ID numbers will be used, data will be kept in secure locations and/or in locked offices. The study team will have access to data that participants' identities could be readily ascertained, such as in screening information and previous participant payment information. Participants names, however will not be used during any data analysis nor will they be part of any published results. Only authorized study personnel will have access to screening and payment information.
The only key connecting participants' data ID to their identities is in REDCap, which is accessible only to trained personnel and is accessed via secure log in.

8. WHO WILL HAVE ACCESS TO STUDY DATA?

Access to study data will be limited to study personnel who have completed the IRB Human Subjects Training and who have been delegated the responsibility of data collection, management, or analyses by the PI.

9. DESCRIBE THE PLANS FOR RETAINING OR DESTROYING STUDY DATA:

Data collected from this study will be retained and destroyed in accordance with state and federal law that requires a 5-year retention period following study closure.

10. FROM WHERE DOES THE EXISTING DATA ORIGINATE?

The existing data comes from Qualtrics survey responses and our Experimental Tobacco Marketplace dataset collected under VT IRB 20-008.

11. PROVIDE A DETAILED DESCRIPTION OF THE EXISTING DATA:

Data for this project is comprised Qualtrics survey data and data from our Experimental Tobacco Marketplace. All data were collected under VT IRB 20-008, including obtaining informed consent.

12. IS THE SOURCE OF THE DATA PUBLIC?

☒ **No,** go to question 13

☐ **Yes,** you are finished with this application

13. WILL ANY INDIVIDUAL ASSOCIATED WITH THIS PROJECT (INTERNAL OR EXTERNAL) HAVE ACCESS TO OR BE PROVIDED WITH EXISTING DATA CONTAINING INFORMATION WHICH WOULD ENABLE THE IDENTIFICATION OF SUBJECTS:

- **Directly** (e.g., by name, phone number, address, email address, social security number, student ID number), or
- **Indirectly through study codes** even if the researcher or research team does not have access to the master list linking study codes to identifiable information such as name, student ID number, etc

or

- **Indirectly through the use of information that could reasonably be used in combination to identify an individual** (e.g., demographics)

☐ **No,** collected/analyzed data will be completely de-identified
☒ **Yes,**

If yes,

Research will not qualify for exempt review; therefore, if feasible, written consent must be obtained from individuals whose data will be collected / analyzed, unless this requirement is waived by the IRB.

Will written/signed or verbal consent be obtained from participants prior to the analysis of collected data? Yes, signed consent has been obtained

This research protocol represents a contract between all research personnel associated with the project, the University, and federal government; therefore, must be followed accordingly and kept current.

Proposed modifications must be approved by the IRB prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects.

Do not begin human subjects activities until you receive an IRB approval letter via email.

It is the Principal Investigator's responsibility to ensure all members of the research team who collect or handle human subjects data have completed human subjects protection training prior to handling or collecting the data.

----------END----------