Document Coversheet

Study Title:

Flavored Tobacco Product Regulation: Behavioral Economic Demand, Visual Attention, and Flavored Tobacco Product Availability

Institution/Site:	Roswell Park Comprehensive Cancer Center
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ROSWELL PARK CANCER INSTITUTE
d/b/a ROSWELL PARK COMPREHENSIVE CANCER CENTER
ELM AND CARLTON STREETS
BUFFALO, NY 14263

TITLE: Flavored Tobacco Product Regulation: Behavioral Economic Demand, Visual Attention, and Flavored Tobacco Product Availability

PRINCIPAL INVESTIGATOR: Amanda J. Quisenberry, Ph.D.

ROSWELL PARK STUDY NUMBER: I 75418

Consent Form Given to Participant Taking Part in a Scientific Research Study

This is a research study. Research studies include only those people who choose to take part. It is important that you read and understand several general rules that apply to anyone that takes part in our study:

1. This study is considered research.
2. Taking part in the study is voluntary.
3. You may withdraw from the study at any time without penalty, loss of any benefits, or access to care at Roswell Park to which you are otherwise entitled.
4. Personal benefit may not result from taking part in the study, but knowledge may be gained that will benefit others.
5. If we become aware of important new findings that relate to your participation or continued participation in this study, we will discuss them with you

The type of study, the risks, benefits, discomforts, and other important information about this study are discussed below.

1. INTRODUCTION:

Determining the level of substitutability of both flavored and unflavored/tobacco flavored e-cigarettes when menthol cigarettes are available and unavailable can help determine if a flavor ban (of either menthol cigarettes and/or flavored e-cigarettes) will lead to cessation and/or harm reduction. This study will evaluate flavored and unflavored tobacco product abuse liability and measures of visual attention. Adult menthol smokers (n = 179) will use an experimental tobacco marketplace (ETM) to purchase tobacco products, with simultaneous eye-tracking measurements of visual attention to flavor-related text and imagery included on tobacco product packaging.

2. WHAT IS THE PURPOSE OF THIS STUDY?

This research study is being done by researchers at Roswell Park. The purpose of this study is to help us learn more about tobacco product purchasing of menthol cigarette smokers. A greater understanding of tobacco product purchasing could help inform possible regulatory actions by the Food and Drug Administration.

3. WHO ELSE WILL BE ON THIS STUDY AND HOW LONG WILL IT LAST?

This study will include about 179 participants locally with a duration of five years. Your participation on this study will be for only one 90-minute visit.

4. WHAT WILL HAPPEN IF YOU ARE ON THE STUDY?

We will ask you some questions to make sure participation in the study is safe for you, including questions about alcohol and drug use. We will also collect information (e.g., age, education) from you that we need to analyze our data. We will give you a detailed description of what it will be like to be in the study and answer any questions you have.

In addition to this consent portion of the session, your participation in this study involves an assessment portion, which will occur after you provide informed consent. During the assessment portion of the session, you will undergo a series of assessments that include measures of tobacco product purchasing, smoking-related behaviors, questions about substance use, and evaluations of the task you completed. In addition, while you complete the tobacco purchasing portion of the session, eye-tracking equipment will be recording your eye movements. You will be seated in a comfortable chair 24-32 inches from a 22-inch computer monitor equipped with the eye tracking system. You will not need to do anything special for the eye-tracking to work; we are interested in your natural eye movements while completing the task. The assessment portion of the session should last approximately one hour.

If you agree to receive text messages from us, we will input your phone number in online software that sends automatic text messages. Your phone number will not be shared with other third parties for any other reason.

5. WHY WOULD YOU BE TAKEN OFF THE STUDY EARLY?

You may be taken off the study for any of the following reasons:

- You do not follow the study schedule or requirements

6. MUST YOU TAKE PART IN OR STAY ON THE STUDY?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with Roswell Park.

7. WHAT RISKS AND DISCOMFORTS ARE INVOLVED?

There will be no direct costs for your participation, although there are risks. One risk is possible embarrassment. This may result from answering questions that you consider sensitive. Some of our questions will ask for information about drug use. In addition, loss of confidentiality is another potential risk of participation. We will make every effort to protect your confidentiality should you participate in this study. There may be other risks that are currently unknown.

If problems occur during the study session, we will determine whether you should continue. If necessary, referrals will be provided. If you have questions concerning the study, please contact Amanda J. Quisenberry, the Principal Investigator at (716) 845-4918 (office).

8. WHAT BENEFITS MAY YOU GET FROM THIS STUDY?

You will not directly benefit from participating in this study. The current study, however, may help provide novel insights into possible regulation that could help curb tobacco use.

9. WHAT IF YOU DO NOT JOIN THIS STUDY?

It is your decision to join. There are no penalties for not taking part in this study.

10. WHAT WILL THIS COST?

There are no costs associated with this study

11. WILL YOU BE PAID FOR JOINING THIS STUDY?

By law, payments to participants are considered taxable income. You will receive compensation outlined below after completion of the relevant tasks.

- $10.00 for completion of the consent portion of the session
- $20.00 for completion of the assessment portion of the session (approximately one hour)
- Parking validation, if you pay to park on campus.

The total compensation that can be earned from participation in this study is $30.00. Payments will be made in gift cards.

It is possible that this research project will result in developing treatments, devices, new drugs, or procedures. If this happens, you understand that you will not receive any financial payment from the resulting use of information gained and developed through your participation in the research study.

12. WHAT IF YOU HAVE QUESTIONS?

You are free to ask questions at any time about this study and to ask for more information from the doctor identified on this consent. For questions, concerns, or complaints about the study you may contact Amanda J. Quisenberry, the Principal Investigator at (716) 845-4918 (office).

If you have questions about your rights as a research participant or you feel you have been injured as a result of your participation in this research study, you can call the Roswell Park Patient Advocate (Support) Office at (716) 845-1365. You should also feel free to contact the Patient Advocate Office at any time while considering participation, during participation or once your participation is complete. This office is unaffiliated with any specific research study. They can help you obtain additional information regarding your research participation and your rights as a research participant or how to proceed should you feel you have been injured as a result of your participation. They are available to discuss any problems, concerns, questions or input you may have.

13. WHAT ABOUT CONFIDENTIALITY?

Confidentiality will be maintained at all times. Your name will not be included on any data that will be used for analysis. You will be assigned a study ID, which will be used in the data instead of your name. All data will be password protected and only accessible to study personnel who have complete human subjects training. Any paper documents (e.g., informed consent) will be kept in locked cabinets in locked offices.

INVESTIGATOR'S STATEMENT:
I certify that to the best of my knowledge the subject/guardian signing this consent form has had the research fully and carefully explained to him/her, and I believe clearly understands the nature, risks, and benefits of participation.

INVESTIGATOR SIGNATURE_____ DATE_____TIME_____

Printed Name of Investigator_____

PARTICIPANT'S STATEMENT OF CONSENT:

By signing below, you agree that:
- You have been told of the reasons for this study.
- You have had the study explained to you.
- You have had all of your questions answered, including those about areas you did not understand to your satisfaction.
- You have carefully read this consent form and will receive a copy of this signed form.
- You willingly give your consent to join in this research study.
- You do not waive any rights you have under federal or state laws and regulations.

PARTICIPANT_____ DATE_____TIME_____

Printed Participant Name_____

☐ N/A ***Witness Signature is needed in the following circumstances:**
☐ Participant cannot write – mark must be made as appropriate.
☐ Participant cannot read - consent has been read to him/her.
☐ Participant cannot understand English and the consent has been verbally interpreted (The witness should be fluent in both English and the language of the participant.)

WITNESS STATEMENT:

The patient has signed this document in my presence.

WITNESS SIGNATURE_____ DATE_____TIME_____

Printed Witness Name: _____

Relationship to Patient: _____

CONSENT HANDLING
Original to CRA-Regulatory with Race/ Ethnicity if applicable
Copy to:
- Patient
- Medical Records