JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH
ASSENT FORM

Study Title: How consumers use flavors to make inferences about Electronic Nicotine Delivery System (ENDS) product qualities and intentions to use (Phase 2)
Principal Investigator: Meghan Moran, PhD

IRB No.: 11186

PI Version Date: April 23, 2020

Details About the Study

What is the purpose of this study?
Research allows us to collect information from people to help us answer questions about health. Through this study, we would like to find out more about tobacco marketing.

Why we are asking you to participate?
We are working with SSRS, a survey research firm, to connect with participants for our online survey. You are being asked to take part in this study because you have previously agreed to be contacted by SSRS about chances to participate in research. We hope to include 2,500 young people like you in this study.

What will happen if you join this study?
If you join this study, you will be asked to complete an online survey. You may take this survey wherever you like – on a computer, laptop, mobile device or other device with internet. The survey will ask you questions about yourself and your experience with tobacco products. You will also be shown five different tobacco ads and asked to tell us your perceptions of those ads. The survey should take about 20 minutes. You do not have to answer any questions that you do not want to.

What are the risks or discomforts of the study?
We do not predict any significant risks to you if you take part in this study. You may become bored during the survey, or may feel uncomfortable answering questions about yourself or your tobacco use. You do not need to answer any questions that you do not wish to, and may stop participating at any time. The survey will not collect any information that identifies you specifically.

What are the potential benefits to being in the study?
There is no direct benefit to you from taking part in the study. However, your participation in the study may benefit young people in society by helping us better understand tobacco product use and tobacco marketing.

Will you be paid if you join this study?

You will receive 150 points for completing this survey. If you do not complete the survey, you will not receive any points.

Ending study participation

You do not have to join this study. It is up to you. You can agree now and change your mind later. You may end your participation at any time. If you wish to end your consent or leave the study, you can navigate away from or close the survey webpage.

What Happens to Data Collected in the Study

Information from this study may be published in professional journals or presented at scientific conferences, but your identifiable information will not be included in any report or presentation. All research staff are committed to protecting your privacy.

What is a Certificate of Confidentiality?

This research is covered by a special protection (called a Certificate of Confidentiality) from FDA. This special protection requires that researchers involved in this study protect your privacy. This means researchers generally cannot provide your name, or any other information that could identify you, to anyone who is not connected with the research. Researchers cannot share your information in court or during other legal proceedings, unless you agree, even if there is a court order for the information. However, in other settings, researchers may share study information that could identify you if:

- you agree to share information (for example, to get medical treatment);
- the study information is used for other scientific research that follows federal law;
- the FDA, which is paying for the study, needs information to check how their research money is being spent; or
- a law requires sharing information (for example, when researchers must report to FDA, or if researchers hear threats of harm to others or reports of child abuse).

The Certificate of Confidentiality does not prevent you from sharing any personal information or information about your involvement in this study with others. For example, you can share that you are in this research study or your history of tobacco use.

The Institutional Review Board (IRB) at Johns Hopkins School of Public Health has reviewed this research. An IRB is a group of people who are responsible for making sure that the rights of participants in research are protected. The IRB may review the records of your participation in this research to ensure that proper rules were followed.

Study Contact and Questions

What is the Institutional Review Board (IRB) and how does it protect you?

This study has been reviewed by an Institutional Review Board (IRB), a group of people including scientists and community people, that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-955-3193 or jhsph.irboffice@jhu.edu.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?

- Call the principal investigator Dr. Meghan Moran, at 410-614-6872 if you have questions or complaints.

- Call or contact the **Johns Hopkins Bloomberg School of Public Health IRB Office** if you have questions about your rights as a study participant. Contact the IRB if you feel you have not been treated fairly or if you have other concerns. The IRB contact information is:

  Address: Johns Hopkins Bloomberg School of Public Health
  615 N. Wolfe Street, Suite E1100, Baltimore, MD 21205
  Telephone: 410-955-3193; Toll Free: 1-888-262-3242
  E-mail: jhsph.irboffice@jhu.edu

Agreeing To Participate

Completing this online survey and submitting it to us means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to participate in this study. You may save or print this information sheet if you wish.

Click 'I agree to participate' to continue on to the survey.

[link to survey – *hyperlinked to phrase 'I agree to participate'*]

Paperwork Reduction Act Statement: The public reporting burden for this collection of information has been estimated to average 2 minutes. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRAStaff@fda.hhs.gov.