OMB# 0910-0810
EXP: 12/31/2024

STUDY 1: ATTACHMENT C1
PARTICIPANT ASSENT FORM

TITLE OF INFORMATION COLLECTION:
The Real Cost Campaign (W3): Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use

Principal Investigator: **Kristen Holtz, PhD**

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Organization: **KDH Research & Communication, Atlanta GA**

Introduction: About this study
The purpose of this research, which will take the form of an online survey, is to explore whether advertisements (ads) designed to prevent youth from using electronic nicotine delivery systems (ENDS, also called e-cigarettes or vapes) are understandable and engaging. There will be a total of up to 300 participants in this study.

The U.S. Food and Drug Administration's Center for Tobacco Products (CTP) is sponsoring this study with youth, ages 13 to 17, from the 48 contiguous U.S. states and the District of Columbia. The mission of the FDA is to promote and protect public health. In conducting this study, FDA does not intend to sell tobacco, nor promote, condone, normalize, or encourage its use. The questionnaires, surveys, and messages in this study are not intended to promote, directly or indirectly, other behaviors that may be a gateway to subsequent risky behaviors, such as illegal drug use, binge drinking and smoking.

KDH Research & Communication will oversee the study implementation. The study will show draft versions of ads to learn if the messages are understood. Tested ads will be close to final versions that still need small edits. Youth will complete a survey to help make the ads final.

What will I do during this study?
You are invited to do an online survey. You will complete the survey on a device such as a mobile phone or computer. You may be asked to view an ad and tell us your opinions about it. You will be one of a group of up to 300 youth participating in this study.

If you are shown an ad, the survey will take up to 20 minutes to complete. If you are not shown an ad, the survey will take up to 10 minutes to complete. You will be asked questions about the ad and your thoughts about tobacco.

You can choose to take part in the study or not, regardless of what other youth choose to do. You can choose to stop taking the survey at any time. You do not have to answer any questions you

do not want to. You will receive the incentive for participating in the study even if you choose to skip questions.

Who will see the information I provide during this study?
We will carefully protect your information and your privacy. Your answers will be kept private to the extent allowable by law. That means we will not share your answers with anyone outside the study unless it is necessary to protect you, or if required by law. Some personal information, like gender, age, race, and ethnicity, will be gathered. Any personal information that identifies you will be destroyed at the end of the study. No one will know what answers you gave us. **Information you share about your tobacco attitudes, beliefs and behaviors will not be shared with others. This includes your parent(s)/guardian(s).**

We will keep answers you provide for five years after the completion of the study. Your answers will be combined with the answers from all the study participants and become the data for this study. The study data will be stored on a password-protected computer or in a locked cabinet. Five years after the completion of the study, we will destroy all study data by securely shredding and permanently deleting records.

Data from this study may appear in professional journals or at scientific conferences. We will not disclose your identity in any report or presentation. Study data may be used in future research. We may share study data with other researchers. But anyone who looks at the study data will not have your name or any other information that could reveal your identity.

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 this 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).

You can share any information you want to with others. For example, you can share that you are in this research study or your history of tobacco use.

Will I be paid for being in this study?
As a token of appreciation, after the survey is submitted, you will receive an incentive in the form of a $10 e-gift voucher or points. The incentive will be delivered via your parent/guardian's account with you and your parent/guardian’s affiliated research panel. There is no cost for taking part in this study. The incentive will be delivered within 30 days of submitting the survey.

What good will come from this study?
This study is not expected to directly benefit you. Your answers will help us make ads about the harms of e-cigarette/vape use.

Could anything bad happen to me during this study?
We do not expect that anything bad will happen to you during this study. We will carefully protect the data you provide. However, as with all studies, there is a chance that privacy could be broken because of an accident or a security breach. If a security breach does occur, the PI will notify you and your parent/guardian through your affiliated research panel.

You will see images and be asked questions related to e-cigarette/vape use and prevention in this study. These images and questions might make you feel uncomfortable. You should talk to your parents, guardian, or school counselors about any concerns you have about how these images made you feel. You should also talk with them about any questions or concerns you have about using e-cigarettes/vapes.

Remember that you can stop participating in this study at any time.

Do I have to be in this study? What if I want to drop out?
You can freely choose to take part in the study or not, regardless of what other youth choose to do. You can choose to stop taking the survey at any time. You do not have to answer any questions you do not want to.

Questions and Contacts: Who do I call if I have questions now or later?
If you have any questions or concerns about this study, you may call Kristen Holtz (404-395-8711) or email at kholtz@kdhrc.com. She is the principal investigator in charge of this study.

If you have questions about your rights as a research participant, please contact the KDH Research & Communication IRB Chair, Dr. Eric Twombly, via email (etwombly@7research.org) or by phone (404-668-3728). An IRB is a group of people who review research studies to protect the rights and safety of research participants. Please keep a copy of this form for your records. If you would like an additional blank copy of this form, you can email Kristen Holtz at kholtz@kdhrc.com.

PLEASE CHECK ONE OF THE BOXES AND SIGN BELOW.

☐ **Yes, I agree to participate in this study. I have read, understand, and had time to consider all of the information above. My questions have been answered and I have no further questions. By checking this box and typing my name on the signature line below, I am electronically signing this consent form.**

☐ **No, I do not agree to participate in this study. I have read, understand, and had time to consider all of the information above. My questions have been answered and I have no further questions.**

*If you choose YES, we will email you the form for your records

Submit

Please click SUBMIT to turn in your consent form.

Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0810. The time required to complete this information collection is estimated to average 2 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. 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.