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

STUDY 1: ATTACHMENT E1
PARENT / GUARDIAN NOTIFICATION AND OPT-OUT INFORMATION

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**

Contact information **404-395-8711 (24 Hours call or text) or kholtz@kdhrc.com**

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

Please read this carefully. Please contact the researchers or opt-out below if you do not want your child to participate in the study. Contact information is listed above.

Introduction: About this study
The purpose of this research is to determine whether ads designed to prevent youth from using electronic nicotine delivery systems (ENDS, also called e-cigarettes or vapes) provide an understandable and engaging message about the harms of e-cigarette/vape use. FDA does not encourage the use or sale of tobacco products.

We are partnering with the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products to conduct a study with youth ages 13 to 17. The study includes youth from across the United States. 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. Your child will complete a survey to help make the ads final. We want to know which ads they think are understandable and engaging. This study plans to have up to 300 participants.

Procedure: What will my child do during this study?
If you forward the study link to your child, they will be invited to complete a survey online. Your child will complete the survey on a device such as a mobile phone or computer.

Your child will be asked screener questions to determine if they qualify for the survey. If your child qualifies for the survey, then they may be asked to view an ad and tell us their opinions about it. If your child IS shown an ad, the survey will take up to 20 minutes to complete. If your child IS NOT shown an ad, the survey will take no longer than 10 minutes. Your child will be asked questions related to tobacco use and attitudes about tobacco. We may combine information your child provides from both the screener and the study survey.

Your child can choose to stop taking the survey at any time. You can also withdraw your consent for your child to participate at any time.

Privacy: Who will see the information my child provides during this study?

We will take care to protect your child's privacy. Your child's answers will be kept private to the extent allowable by law. That means we will not share your child's answers with anyone outside the study unless it is necessary to protect them, or if required by law. Some personal information, like gender, age, race, and ethnicity, will be gathered. We will also record your child's thoughts, opinions, and reactions to ads designed to prevent youth e-cigarette/vapes use. Any personal information that identifies your child will be destroyed within three months after the last person completes the survey. **Information your child shares about their tobacco-related attitudes, beliefs, and behaviors will not be shared with parent(s)/guardian(s).**

All de-identified data will be kept for five years after the completion of the study. Data will be stored on a password-protected computer or in a locked cabinet. Five years after completion of the study, we will destroy all the data by securely shredding paper documents and permanently deleting electronic information.

Data from this study may appear in professional journals or at scientific conferences. We will not disclose your child's identity in any report or presentation. Data from this study may also be used in future research or shared with other researchers. However, anyone who looks at this data will not have your child's name or any other information that could reveal his/her identity.

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

- You or your child 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 study staff must report to FDA, or if study staff hear threats of harm to others or reports of child abuse).

You or your child can share any information you want to with others. For example, you can share that your child is taking part in this research study or your child's history of tobacco use.

Reimbursement: Will my child be paid for being in this study?
As a token of appreciation, after the survey is submitted, your child will receive an incentive in the form of a $10 e-gift voucher or points. The incentive will be delivered via your account with your 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.

Study Benefits: What good will come from this study?
This study is not expected to directly benefit you or your child. Your child's feedback will help us create ads to prevent youth e-cigarette/vape use.

Anticipated Risks: Could anything bad happen to my child during this study?

We will carefully minimize the potential risks of participating in this study. However, as with all research, there is a chance that privacy could be broken. However, all data will be stored on a password-protected computer or in a locked cabinet and protected. If a security breach does occur, the PI will notify you and your child through your affiliated research panel.

You child will see images and be asked questions related to e-cigarette/vape use. These images and questions might make your child feel uncomfortable. Your child may want to talk to you about how the ads made them feel. Your child may also want to talk with you about any questions or concerns they have about using e-cigarettes/vapes. If you or your child have any questions or concerns about e-cigarette/vapes or are interested in quitting tobacco products, please visit *The Real Cost* website for resources. If you or your child have any questions about this study, you may call or email the Principal Investigator at the telephone number or email address listed on the first page of this document.

Participation and Withdrawal: Does my child have to be in this study? What if my child changes his/her mind?
This study is completely voluntary. You and your child can freely choose to take part in the study or not, regardless of what other parents, guardians, or youth choose to do. You can also withdraw permission for your child to participate at any time with no penalty or loss of benefits. Contact the Principal Investigator or the study staff at the telephone number or email address listed on the first page of this document if you want to remove your child from the study. Your child will still receive the incentive even if they choose not to answer some questions during the online survey.

Research Questions and Contacts: Whom do I call if my child or I have questions?
If you have any questions or concerns about this study, please contact the principal investigator or the study staff at the telephone number or email address listed on the first page of this document.

The KDHRC IRB has reviewed this research. An institutional review board (IRB) is a group of people who are responsible for ensuring that the rights of participants in research are protected. The IRB does not conduct the study but ensures that proper procedures were followed.

If you have questions about your rights as a study participant or concerns about how you are treated in the study, you may contact Eric Twombly, Chair of the KDHRC IRB, at etwombly@7research.org

IMPORTANT:

If you DO want your child to participate, forward [the link] to him or her.

If you DO NOT want your child to participate, you must select the option below or contact the principal investigator at the telephone number or email address listed above.

○ **I do NOT want my child to participate in this study.**

Submit

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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.