

APPENDIX B
PARENT / GUARDIAN NOTIFICATION AND OPT-OUT INFORMATION

TITLE OF INFORMATION COLLECTION:

The Real Cost Campaign: Media Tracking Study

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Please read this carefully. **Please contact the Principal Investigator within 24 hours 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 better understand changing knowledge, attitudes, beliefs, and behaviors of youth in relation to tobacco products. We will also test whether ads designed to prevent youth from using tobacco products are understandable and engaging.

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. Your child will complete a survey about their knowledge and attitudes towards tobacco products. Your child will also see ads and answer questions about them. We want to know which ads your child thinks are understandable and engaging. This study plans to have up to 2,000 participants.

Procedure: What will my child do during this study?

If you forward the study link to your child, he or she will be invited to complete a survey online. Your child will complete the survey on his/her own device such as a mobile phone or computer.

Your child will be asked screener questions to determine if he or she qualifies for the survey. If your child qualifies, your child will be asked to complete the survey, view an ad, and tell us their opinions about it. The survey will take no more than 17 minutes to complete. 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. Your child does not have to answer any questions that he or she does not want to. Your child will still receive the token of appreciation even if your child chooses not to answer some questions.

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 individual answers will be kept private to the extent allowable by law. That means we will not share your child's individual answers with anyone outside the study unless it is necessary to protect him/her, 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 TV ads designed to prevent youth tobacco use. Any personal information that identifies your child will be destroyed within three months after the last person has completed the survey. **Information your child shares about their tobacco-related attitudes, beliefs and behaviors will not be shared with parent(s)/guardian(s).**

All information from this study will be destroyed three years after the completion of the study. Until that time, it will be stored on a password-protected computer. Three years after completion of the study, we will destroy all study information by securely shredding paper documents and permanently deleting electronic information.

Data from this study will only ever be reported in aggregate. 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. However, anyone who looks at this data will not have your child's name or any other information that could reveal his/her identity.

Reimbursement: Will my child be paid for being in this study?

As a token of appreciation, your child will receive a \$5 Visa gift card awarded through your affiliated research panel after your child submits the survey. There is no cost to you or your child for taking part in this study. Your child will receive the token of appreciation 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. However, your child's feedback will help us decide what ideas, images, messages, and ads are understandable and engaging.

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

We will take care to minimize the potential risks of participating in this study. However, as with all research, there is a chance that privacy could be compromised. However, in order to protect against this, the data will be stored on a password-protected computer. *All information will be destroyed three years after the completion of the study by securely shredding and permanently deleting records.*

Though unlikely, there is a small chance that your child may experience some discomfort from potentially sensitive questions. Participation in this study is voluntary; your child can refuse to answer questions in the survey and will still receive \$5 Visa gift card in appreciation.

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 choose to take part in the study or not, regardless of what other parents, guardians, or teens 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 token of appreciation even if he/she chooses 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.

This research is covered by a special protection (called a Certificate of Confidentiality), as required by the Department of Health and Human Services. This special protection requires that researchers involved in this study protect your privacy. This means researchers generally cannot provide your child's name, or any other information that could identify your child, 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).

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 vaping or tobacco use.

IMPORTANT:

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



for reducing burden, to PRASStaff@fda.hhs.gov.