

**APPENDIX C
YOUTH ASSENT FORM**

**TITLE OF INFORMATION COLLECTION:
The Real Cost Campaign: Media Tracking Study**

FDA Project Lead: Food and Drug Administration (FDA)
Center for Tobacco Products (CTP)

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Please read this form carefully. **You must submit this form by clicking the button at the bottom of the last page before you can take part in the study.**

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 in multiple areas across the United States. The study will contain a survey about your knowledge and attitudes towards tobacco products. You will see ads and answer questions about them We want to know which ads you think are understandable and engaging.

What will I do during this study?

You are invited to do a survey. You will complete the survey on your own device such as a mobile phone or computer. You will be one person in a group of up to 2,000 participants in this study.

The survey will take no more than 17 minutes to complete. You will be asked questions related to tobacco use and your attitudes about tobacco.

You can choose to take part in the study or not, regardless of what others 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 still receive a token of appreciation for participating in the study even if you choose to skip questions.

Who will see the information I provide during this study?

We will take care to keep your answers to the survey questions private. 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 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 three years after the completion of the study. The answers to the survey questions will be the data for this study. We will store the data on a password-protected computer and destroy the data and all other study information three years after the completion of the study by securely shredding paper documents and permanently deleting electronic information.

Data from this study may appear in professional journals or at scientific conferences but only combined data from all participants. We will not disclose your identity in any report or presentation. Data from this study may be used in future research. Anyone who looks at this data will not have your name or any other data that could reveal your identity.

Will I be paid for being in this study?

If you are eligible and complete the survey, you will a \$5 Visa gift card as a token of appreciation. There is no cost for taking part in this study. You will receive the gift card within 30 days of submitting the survey.

What good will come from this study?

This study is not expected to directly benefit you. However, your feedback will help us decide what ideas, images, messages, and ads are understandable and engaging.

Could anything bad happen to me during this study?

We will take care to 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. However, to protect against this, the data will be stored on a password-protected computer.

All images in the ads we share will be presented in the context of tobacco use prevention. 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 tobacco products. If you have any questions about this research study, you may call or email the Principal Investigator at the telephone number or email address listed on the first page of this form.

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 teens 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 still receive a token of appreciation for participating in the study even if you choose to skip questions.

Questions and Contacts: Who do I call if I have questions now or later?

If you have any questions 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 form.

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 KDHRC IRB has reviewed this research. 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 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.

I have read, understand, and had time to consider all of the information above. I have no more questions about this study at this time. I agree to take part in this study.

Do you want to continue?

- Yes, I want to participate.***
- No, I do NOT want to participate.**

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

Submit

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 2 minutes per response to complete this form (the time estimated to read and complete). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRASStaff@fda.hhs.gov.