

Attachment A: Parental Notification and Opt-Out Form

PARENT / GUARDIAN NOTIFICATION AND OPT-OUT FORM

**TITLE OF INFORMATION COLLECTION:
FDA Tobacco Prevention Broad Quantitative Research Package**

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Please read this form carefully. **Please contact the researchers 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 determine whether TV ads designed to prevent youth from using tobacco provide an understandable and engaging message about the harms of tobacco 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 TV ads to learn if the messages are understood. Tested TV ads will be close to final versions that still need small edits. Your child will complete a survey to help make the TV ads final. We want to know which TV ads she/he thinks are understandable and engaging. This study plans to have up to 5,500 participants.

Procedure: What will my child do during this study?

Your child is now 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 may be asked to view a TV ad and tell us his/her opinions about it. The survey will take up to 20 minutes to complete, plus the time needed to complete the screener. If your child IS NOT shown a TV 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.

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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 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 data will be kept for three years after the completion of the study. It will be stored on a password-protected computer or in a locked cabinet. Three 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.

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

Your child will receive the point amount equivalent to approximately \$10.00 from <<COMPANY>> after he or she submits the survey. There is no cost for taking part in this study. Your child will receive an email with a link to 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 TV ads about the harms of tobacco use.

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. The data will be stored on a password-protected computer or in a locked cabinet. Three years after the completion of the study, we will destroy all of the data by securely shredding and permanently deleting records.

Your child may want to talk to you about any concerns he/she has about how the ads made him/her feel. Your child may also want to talk with you about any questions or concerns he/she has about using tobacco. 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 form.

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

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page 1 of this form if you want to remove your child from the study. Your child will still receive the points 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 form.

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 Ed Morgan, Chair of the KDHRC IRB, at emorgan593@aol.com

IMPORTANT:

If you DO NOT want your child to participate, you must contact the principal investigator within 24 hours or the study staff at the telephone number or email address listed above.

If you DO want your child to participate, do nothing.

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 1 minute 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 PRStaff@fda.hhs.gov.