
**ONLINE QUANTITATIVE STUDY OF YOUTH REACTIONS TO
ROUGH-CUT ADVERTISING DESIGNED TO PREVENT YOUTH
TOBACCO USE AMONG GENERAL MARKET YOUTH (WAVE 2)**

PARENTAL OPT-OUT FORM

Please read this form carefully. You can ask as many questions as you want. If there is any information you do not understand, researchers will be happy to explain it to you. **Please contact the researchers within 24 hours of receiving this document if you do not want your child to participate in the study. Your child has already qualified to participate and will automatically be sent a link to the study 24 hours after they completed qualification. Your child's responses can still be removed after this time period. Contact information is listed on the last page of this form.**

Introduction: About this study

The **purpose** of this study is to determine whether advertisements designed to prevent youth from using tobacco provide an understandable and engaging message about the harms of tobacco use.

FCB is an advertising company partnering with the U.S. Food and Drug Administration's Center for Tobacco Products (CTP) to conduct an online copy testing study with youth nationwide. The study involves showing draft versions (i.e., "rough-cuts") of television advertisements to consumers to determine if the messages are understood. Youth participating in this study will view rough-cut advertisements we have developed to help prevent youth from using tobacco. We will collect their thoughts and opinions about these advertisements to determine which advertisements provide an understandable and engaging message about the harms of tobacco use.

Procedure: What will my child do during this study?

Your child will be part of a group of 1,800 youth participating in an online study. The study will take place from [DATE RANGE] on a secure website that is password protected. The study will take no longer than 10 minutes. During that time, your child will answer questions on the screen about the advertisements he/she is shown. Your child's answers will be kept private to the extent allowable by law.

This study is completely voluntary. You can choose whether or not to give permission for your child to take part in this study. Your child can also choose whether or not to take part in or complete this study.

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

We will take care to protect your child's privacy. This study will take place on a secure website that is password protected and will not display your child's personal information. 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 it is

required by law. Although some personal information will be gathered (e.g., gender, age, race, thoughts, opinions and reactions to messages and ideas designed to prevent youth from using tobacco) no personal identifiers (e.g. full name and email address) will be maintained after screening. This means that after your child agrees to participate, his/her answers will not be connected to his/her name or contact information. No one will know what answers your child gave us.

If your child agrees to participate, some data collected during screening may become part of the final data set, and all data collected during screening and during the study will be kept for three years and stored on a password protected computer or in a locked cabinet. After that, all data will be destroyed either by secure shredding or permanent deletion of electronic information.

We will not share information with anyone outside of the study unless it is necessary to protect you or your child, or if it is required by law. **Information your child shares about their tobacco-related attitudes, beliefs and behaviors will not be shared with others, including you.**

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.

Token of Appreciation: Will my child be paid for being in this study?

Everyone who takes part in this study will receive a \$20 eGift card as a token of appreciation for participating in the study.

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 determine whether the rough-cut advertisements we developed provide an understandable and engaging message about the harms of tobacco use.

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

We will take care to protect the information your child provides. However, as with all studies, there is a chance that privacy could be broken as a result of an accidental error or a security breach.

Your child may want to discuss tobacco use or tobacco use prevention with you. Some of the images your child may see during this study may be graphic or possibly disturbing to your child, but within the context of tobacco prevention. Your child may also have questions or concerns about the images or concepts he/she sees during this study. If your child becomes upset or wants to stop participating, **your child may stop participating in this study at any time.**

All information will be kept private to the extent allowable by law and will not be shared with anyone outside this study unless it is necessary to protect you or your child, or if required by law.

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. Your child is allowed to stop participating at any time. Your child does not have to answer any questions he/she does not want to. Your child will receive the \$20 token of appreciation for participating in the study even if he/she chooses to not answer some questions.

Research Questions and Contacts: Whom do I call if my child or I have questions?

If you have any questions about this study, you may call Charlie Cook at FCB (212-885-2987) or Tesfa Alexander at CTP (301-796-9335). If you have questions about your or your child's rights as a research participant, please contact Dr. Bruno Anthony, IRB chair (410-371-7548), and reference IRB #_____.

Respondent ID#:

IMPORTANT:

If you do not want your child to participate, you must contact Shannon Crocker at Marketing Workshop.

Phone: (800) 284-7707 x 238

Email: TeenSurvey@mwshop.com

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete the Parental Opt-out Form (the time estimated to read and review). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRASStaff@fda.hhs.gov.