

General Market Campaign: Wave 3 Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use

PARENTAL CONSENT / 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 a minimum of 24 hours after they completed qualification. Contact information is listed on the last page of this form.

Introduction: About this study

The **purpose** of this research 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. FDA does not encourage the use or sale of tobacco products.

Procedure: What will my child do during this study?

Your child will be part of a group of up to 1,292 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.**

Although you will not have access to your child's answers, you will be given a blank copy of the questions your child will be asked, upon request.

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.

Will my child be paid for being in this study?

Your child will receive a \$20 eGift card as an incentive 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. We will take care to protect the information you provide. However, as with all studies, there is a chance that privacy could be broken because of an accidental error or a security breach. In the event a breach occurs, all participants will be contacted and notified as to the extent of the breach, any damages incurred, and future potential risks; contact information for additional inquiries will also be provided.

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. He or she can choose to not answer the questions and still will receive the full incentive amount.** As noted above, 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 does not have to answer any questions he/she does not want to. Your child will receive the \$20 eGift card 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 David Cortés at FCB (212-885-3743). If you have concerns about your or your child's rights as a research participant in the study, you may contact RIHSC at 301-796-9605, or at RIHSC@fda.hhs.gov and reference RIHSC # 16-034T. The Research Involving Human Subjects Committee (RIHSC) at the Food and Drug Administration has reviewed this research. RIHSC is an institutional review board, a group of people who are responsible for assuring that the rights of participants in research are protected. The RIHSC may review the records of your participation in this research to assure that proper procedures were followed.

Respondent ID#:

IMPORTANT:

If you do not want your child to participate, you must contact Marketing Workshop within 24 hours.

Phone: (800) 284-7707 x 201

Email: TeenSurvey@mwshop.com

Paperwork Reduction Act Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete the Parental Consent / Opt-Out Form (the time estimated to read, review, 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.