

RETAIN FOR YOUR RECORDS
OMB Control Number 0910-0674

PARENT/GUARDIAN INFORMED CONSENT FORM

TITLE OF INFORMATION COLLECTION: Quantitative Study of Youth Reactions to Rough-Cut Advertising Designed to Prevent Smokeless Tobacco Use Among Rural Youth

Sponsor: The Food and Drug Administration's (FDA) Center for Tobacco Products (CTP)

Principal Investigator: Kara Marsh, PhD

Telephone: 571-858-3757 (24 Hours)

**Address: Fors Marsh Group, LLC (FWA00011194)
1010 N. Glebe Road, Suite 510
Arlington, VA 22201**

On <<DATES>> students at <<SCHOOL>> will have the opportunity to participate in research being conducted on campus. The goal of this study is to understand what youth think about several rough-cut advertisements that are designed to prevent smokeless tobacco use. Students who take part in the research will receive a \$20 prepaid gift card for their time.

You are receiving this letter because you are the parent or legal guardian of a child who is eligible to take part in this study. Your son has agreed to participate, but your permission is required for him to do so.

Please read this form carefully. It contains important information about this research study. You can ask as many questions as you want. If there is anything you do not understand, we will be happy to answer your questions. **You must sign this form and have your son return it to study staff at his school before he can take part in the study.**

Introduction: About this study

The goal of this study is to understand what youth think about several rough-cut advertisements meant to reduce youth tobacco use.

Sensis is an advertising company partnering with the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) to create a campaign. We would like your thoughts to help us create ads to prevent teens like your son from using tobacco. We are working with two research partners, Fors Marsh Group and the Michael Cohen Group. We plan to conduct surveys in schools around the country with male youth 12 to 17 years of age.

Procedure: What will my son do during this study?

Your son has been invited to take part in surveys. Surveys are a form of research used to gather opinions on a specific topic. Your son will be asked to share his thoughts on smokeless tobacco and may be asked to view and provide feedback on up to two rough-cut advertisements designed to prevent teens from using smokeless tobacco. The survey will be administered on a tablet or computer and will take about 20 minutes.

Study Benefits: What good comes from this study?

There is no direct benefit to you or your son. However, your son's feedback will help us decide what types of advertisements may prevent youth tobacco use.

Incentive: What will my son get for being in this study?

Your son will receive a \$20 prepaid gift card for taking part in the survey. There is no cost to you or your son for taking part in this study. Your son does not have to answer any questions that he doesn't want to. He will receive the \$20 gift card even if he chooses not to answer some questions.

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

The risks for taking part in the study are low. Some of the images he sees during the study may be graphic or disturbing. Your son may want to discuss tobacco use or tobacco prevention with you. He may also have questions or concerns about the images or videos he sees during this study. If your son becomes upset or wants to stop participating, **he may stop participating in this study at any time.**

We will take care to minimize any risks of participating in this study. However, as with all research, there is a chance that privacy could be breached. For example, despite the best efforts of the research team to keep the information we collected during the study private, a breach may occur as a result of accidental human error or hacking. In the event a breach occurs, all participants will be notified as to the extent of the breach, any damages incurred, and future potential risks; contact information for additional inquiries will also be provided.

If you or your son have any questions about this research study, you may call Kara Marsh of Fors Marsh Group at 571-858-3757 or email a study representative at pi@forsmarshgroup.com.

Privacy: Who will see the results of this study?

Only the authorized research staff will have access to your son's responses. Your son's name and other personal information will not be linked to your responses. We will be very careful to only let people working on the study see the responses your son provides, which will not be linked back to any personal information that can be used to identify him. Everything your son shares will be kept private to the extent allowed by law (e.g., abuse, neglect, self-harm, etc.). This means that we will not share any information your son provides with anyone outside the study unless it is required to protect him, or if required by law. **Please note that we will not share information your son provides about his tobacco-related attitudes, beliefs and behaviors with anyone outside of the research team, including parents/guardians, teachers, and other school staff.**

FDA does not encourage the use or sale of tobacco products. It is illegal in most states for adolescents younger than 18 years old to use tobacco, and it is illegal in all states for adolescents under 18 to buy tobacco.

All of the information we collect, including all of your son's survey responses and data collected during screening, will be kept for at least three years. The information will be stored on a password-protected computer and/or in locked cabinets that only the research team can access. Retained data will not contain any information that could identify you. After three years, all of the collected data will be destroyed by securely shredding documents or permanently deleting electronic information.

Results from this study may appear in professional journals or at scientific conferences. No individual participants will be identified or linked to the results. We will not disclose your son's identity in any report or presentation. Results may also be used in future research or shared with other researchers. Other researchers will not have your son's name or any identifying information.

Participation and Withdrawal: Does my son have to be in this study? What if he changes his mind?

Your son can choose to take part in the study or not, regardless of what other students choose to do. Your son can choose to leave the survey at any time. Your son does not have to answer any questions he does not want to. This study is completely voluntary. Your son can stop participating at any time. He will receive the \$20 prepaid gift card for his participation in the survey even if he chooses to stop participating or chooses not to answer some questions.

Who do I contact if I have questions about the study?

If you have questions or concerns about the study, you can
contact: Kara Marsh, Fors Marsh Group
571-858-3757

pi@forsmarshgroup.com

If you have questions about your rights as a research participant, please contact FDA IRB RIHSC (OC_RIHSC@fda.hhs.gov), and reference IRB # [redacted]. An IRB is a group of people who review research studies to protect the rights and safety of research participants. Please keep a copy of this form for your records. If you would like an additional blank copy of this form, you can email Kara Marsh at pi@forsmarshgroup.com.

PLEASE CHECK ONE OF THE BOXES AND SIGN BELOW.

Yes, I agree for my son to participate in this study. I have read, understand, and had time to consider all of the information above. My questions have been answered and I have no further questions.

No, I do not agree for my son to participate in this study. I have read, understand, and had time to consider all of the information above. My questions have been answered and I have no further questions.

Parent/Guardian Signature

Date

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 Parent/Guardian Informed Consent 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 PRStaff@fda.hhs.gov.