

RETAIN FOR YOUR RECORDS
OMB Control Number 0910-0674

YOUTH ASSENT FORM FOR SURVEYS

AGES 12 – 17

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

You are being asked to take part in this study because you are at-risk for using smokeless tobacco. This form explains the study. After reading this form, you can decide to be in the study or you can decide not to be in the study. Either choice is OK. If you decide to start the study and then change your mind, you can stop being in the study at any time.

Please ask the study staff to explain anything you do not understand. They will answer all the questions you have. You can ask questions about the study at any time. **You must submit this form before you can take part in the study.**

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 you 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.

What will I do during this study?

Study staff will tell you when and where your assigned survey is scheduled. During the surveys, you will be asked some questions about smokeless tobacco and some participants will be asked to view and provide feedback on up to two rough-cut advertisements designed to prevent teens from using smokeless tobacco. The surveys will be administered on tablets or computers and will last about 20 minutes.

Study Benefits: What good comes from my participation?

There is no direct benefit to you. Your feedback will help us decide what types of advertisements may prevent youth tobacco use.

Incentive: What will I get for being in this study?

You will receive a \$20 prepaid gift card for participating in the survey. You do not have to answer any questions that you don’t want to. You will receive the \$20 for your time even if you choose not to answer some questions.

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

The risks for taking part in the study are low. Some of the images you see during the study may be graphic or disturbing. 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 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 have any questions before, during or after the survey, you can ask the survey administrator or other representatives from Fors Marsh Group or Michael Cohen Group. You can also talk to your parent(s)/guardian(s) or a teacher or school counselor. If you have any questions about this study, you may call Kara Marsh of Fors Marsh Group at 571-858-3757 or talk to one of the study staff at your school. **Remember that you can stop being in this study at any time.**

Privacy: Who will see the results of this study?

Only the authorized research staff will have access to your responses. Some personal information, like your first name and last initial, will be gathered, but no personal information will be kept after screening. Your name will not be linked to your responses. We will be very careful to only let people working on the study see the responses you provide, which will not be linked back to any personal information that can be used to identify you. The survey responses will not be shared with your parent(s)/guardian(s) or anyone at your school. Everything you share will be kept private to the extent allowed by law. This means that we will not share any information you provide with anyone outside the study unless it is required to protect you, or if required by law. **What you choose to share about your tobacco-related attitudes, beliefs and behaviors will not be shared with anyone outside the research team, including your parent(s)/guardian(s), 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 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 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 name or any identifying information.

Participation and Withdrawal: Do I have to be in this study? What if I want to stop participating?

This study is completely voluntary. You can stop at any time. You also do not have to answer any questions that you do not want to. You will receive the \$20 prepaid gift card even if you choose 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. If you would like a copy of this form, you can ask study staff who are at your school for a paper copy.

- Yes, I agree 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 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.**

Submit

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 Youth Assent 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.