

YOUTH ASSENT FORM FOR FOCUS GROUPS AGES 12 – 17

TITLE OF INFORMATION COLLECTION: Rural Smokeless Creative Concept Testing – Focus Groups with Rural Youth

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

Principal Investigator: Kara Marsh, PhD

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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 advertising ideas 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 hold twenty-four focus groups with male youth 12 to 17 years of age in different places.

What will I do during this study?

The focus groups will take place in your school during the school day. Study staff will tell you when and where your assigned group is scheduled. During the group session, you will be asked to share your thoughts with the focus group moderator (or interviewer) and the other group members about advertising ideas to prevent teens like you from using smokeless tobacco. The group will last about 90 minutes.

There will be other people in the room observing the group. They will take notes and listen, but they won’t bother you. You will only be talking to the interviewer and the other group members.

Study Benefits: What good comes from my participation?

There is no direct benefit to you. Your feedback will help us decide what ideas, images, and messages may prevent youth tobacco use.

Token of appreciation: Will I be paid for being in this study?

You will receive \$25 as a token of our thanks for being in the focus group. You do not have to answer any questions that you don't want to. You will receive the \$25 for your time even if you choose not to answer some questions.

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

We will be very careful to only let people working on the study see your information. There is a small risk that others might find out what you say, despite all of our best efforts.

Because this is a group session, people may share private thoughts that they would not want shared with others outside the group. We ask that you respect the other group members' privacy and do not share what is said with people outside of the group. We will ask the other group members to do the same thing.

If you have any questions about tobacco use or prevention before, during or after the group, you can ask the group leader. 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?

Everything you say during the focus group can be heard by the other group members, the group leader, research assistants and FDA study monitors. All group members will be asked to keep what is said during the group private.

The focus groups may be live streamed so that other researchers who could not travel can watch too. This video will not be recorded and will be used only for real-time observation. Live streaming is a method of viewing the focus group remotely via the internet without recording it - similar to Skype or FaceTime. You will be told at the start of the focus group if it is being live streamed. The focus groups will also be audio recorded and transcribed. You will have the chance to choose not to be audio recorded at the start of the focus group.

Only the focus group moderator, staff from Sensis, and researchers from Fors Marsh Group and the Michael Cohen Group will have access to your responses. Your name and other personal information will not be linked your responses. This means that no one outside of the research team will know what you said. Everything you share will be kept private to the extent allowed by law. This means that we will not share anything you provide with anyone outside the study unless it is required to protect you, or if required by law. However, if you show a direct threat of harm to yourself or others, we have the right to take action out of concern for you and concern for others. **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.**

All of the information we collect, including anything you say in the focus group and data collected during screening, will be kept for three years. The information, audio files and transcripts will be stored on a password-protected computer and/or in locked cabinets that only the research team can access. We will collect some personal information from you like your age and race but we will not collect any information that could identify you, like your full name, address, or social security number. 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 data 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 can decide not to participate at any time by contacting Kara Marsh of Fors Marsh Group at 571-858-3757 or by talking to one of the study staff at your school.

You also do not have to answer any questions that you do not want to. You will receive the \$25 for your time in the focus group 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 any questions or complaints about your rights as a research participant you may contact Chesapeake IRB at 410-884-2900 (collect), by email at adviser@irbinfo.com, or by mail at Study Subject Adviser, Chesapeake IRB 7063 Columbia Gateway Drive, Suite 110, Columbia, MD 21046. An IRB is a group of people who review research studies to protect the rights and safety of research participants. Please reference the following number when contacting the Study Subject Adviser: **ProXXXXXX**.

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- 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.**

Please enter your email if you would like the study staff to email you a copy of this form for your records:

Submit

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete the Informed 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.