

YOUTH ASSENT FORM FOR FOCUS GROUPS AGES 12 – 17

TITLE OF INFORMATION COLLECTION: Rural Smokeless Focus Groups – Strategic Concept Testing with Rural Adolescent and Young Adults

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
1010 N. Glebe Road
Suite 510
Arlington, VA 22201

You are being asked to be in this research 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 to not 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 principal investigator or 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 purpose of this study is to conduct research to understand what youth think about different kinds of messages and ideas designed 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 an anti-tobacco campaign. We want your help to create ads that can help prevent youth from using tobacco. We are working with a research partner, Fors Marsh Group. The plans are to hold sixteen focus groups with male youth 12 to 17 years of age.

What will I do during this study?

You will be asked to complete an activity on your own prior to the focus group. Don’t worry; this will not be homework like school homework. We will ask you to take an online questionnaire about your attitudes and beliefs on smokeless tobacco. The survey will take approximate 10-15 minutes to complete.

The focus group will take place in a local facility such as a community center or hotel conference center for 90 minutes. During the group session, you will be asked to talk with the interviewer and the other group members about different advertising ideas to prevent other teens like you from using smokeless tobacco.

The focus groups will be livestreamed for onsite research staff observing in a separate room and for research staff who will be observing offsite. This video will not be recorded and will be utilized only for real-time observation. The interview will be audio recorded and transcribed for study-related purposes. You will be given an opportunity to opt out of being audio recorded at the beginning of the interview.

The tapes will be destroyed once the interviews have been transcribed. Only the research team and people performing this analysis will have access to the information you provide in the study. We will not disclose your identity in any report or presentation.

Anticipated Benefits: What good comes from my participation?

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

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

You will receive up to a \$50 token of appreciation, which includes \$40 for participating in the 90 minute focus group plus an additional \$10 for completing your homework assignment. You will only receive the \$10 homework incentive if you have completed the assignment. Additionally, your mom/dad/guardian will receive \$25 for driving you to the focus group location.

You do not have to answer any questions during the interview that you don't want to. You will receive the \$40 incentive for your participation in the focus group 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, but there is a small risk that others might find out what you say, despite everyone's 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 everyone's privacy and do not share what is discussed with people outside of the group and we will ask the other group members the same thing.

You may also have questions about tobacco use or tobacco use prevention before, during or after this study. You can ask the group leader any questions you have about this study. You can also talk to your parent(s)/guardian(s) or a teacher or school counselor.

If you have any questions about this research study, you may call Kara Marsh of Fors Marsh Group at 571-858-3757 or [click here](#) to email a study representative. **Remember that you can stop participating in this study at any time.**

Privacy: Who will see the results of this study?

Only the focus group moderator, the Sensis advertising agency, and researchers from Fors Marsh Group will have access to the information you provide in this study. Everything you share will be kept private to the extent allowable by law. This means that we will not share any information you provide with anyone outside the study unless it is necessary to protect you, or if required by law. **Information you share about your tobacco-related attitudes, beliefs and behaviors will not be shared with your parent(s)/guardian(s).**

The focus groups will be livestreamed; however, this video will not be recorded and will be utilized only for real-time observation. The interview session will be audio recorded and transcribed for study-related purposes. You will be given an opportunity to opt out of being audio recorded at the beginning of the interview. The report generated using the audio transcripts will not link your comments directly to you or include your full name, and no one outside of the researchers will know what you said during the interview. Comments containing private or personally identifiable information will be removed from the transcripts.

The audio files and transcripts will be stored on a password-protected computer and/or in locked cabinets that are only accessed by the research team. 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, address, social security number) will be collected during the interview.

All of the information we collect, including anything you say in the interview and data collected during screening, will be kept for a period of three years and stored on a password-protected computer or a locked cabinet. After three years, all of the collected data will be destroyed either by the secure shredding of documents or the permanent deletion of electronic information.

Data from this study may be published in professional journals or at scientific conferences, but no individual participant will be identified or linked to the results. We will not disclose your identity in any report or presentation.

The investigators may also use data from this study in future research and/or share data with other researchers. Other investigators 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 participating at any time. You can revoke your consent to participate at any time by contacting Kara Marsh of Fors Marsh Group at 571-858-3757 or [click here](#) to email a study representative.

You also do not have to answer any questions you do not want to. You will receive the \$40 incentive for your participation in the interview session 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

[Click here to email](#)

If you have any questions or complaints about your rights as a research participant 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: Pro00009016.

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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.**

Print

Save

Please print and/or save 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 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 PRStaff@fda.hhs.gov.