

PARENT/GUARDIAN INFORMED CONSENT FORM FOR FOCUS GROUPS

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)

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Arlington, VA 22201**

If you are the parent or legal guardian of a child who may take part in this study, your permission and the permission of your child will be needed. When “you” appears in this form, it may refer to you or your child.

Please read this form carefully. 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 submit this form before your child can take part in the study.**

Introduction: 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 to get a better understanding of your son and other young males to be able to create an effective campaign that can help prevent youth from using tobacco. We are working with a research partner, Fors Marsh Group, to conduct this effort. The plans are to hold sixteen focus groups with male youth 12 to 17 years of age. The plans are to have up to a total of 128 youths take part.

Your Son’s Role in This Study: What will my son do during this study?

Your son will be asked to complete an activity on his own prior to the focus group session. This “homework assignment” will be an online questionnaire about various attitudes and beliefs regarding smokeless tobacco. The survey will take approximate 10-15 minutes to complete.

The focus group session will take place in a local facility such as a community center or hotel conference center for 90 minutes. Your son will be asked to participate in the group by talking with both the moderator and the other group members. Your son and other group members will be asked to evaluate and discuss various ideas to be utilized in a smokeless tobacco usage prevention campaign.

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 focus group will be audio recorded and transcribed for study-related purposes. Your son will be given an opportunity to opt out of being audio recorded at the beginning of the session. The audio tapes will be destroyed once the focus groups have been transcribed.

Only the research team and people performing this analysis will have access to the information your son provides in the study. We will not disclose your son's identity in any report or presentation.

Anticipated Benefits: What good comes from my son's participation?

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

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

Your son 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 the homework assignment. Your son will only receive the \$10 homework incentive if he completes the assignment. Additionally, you (or the accompanying parent/guardian) will receive \$25 for transporting your son to the group.

Your son does not have to answer any questions during the focus group that he doesn't want to. He will receive the \$40 incentive for his participation in the focus group even if he chooses not to answer some questions.

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

We will take precautions to minimize the potential risks of participating in this study. However, as with all research, there is a chance that privacy could be compromised. For example, despite the best efforts of the research team to maintain the privacy of information collected during the study, a privacy/data breach may occur from inadvertent human error or as a result of hacking.

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 your son respects everyone's privacy and does not share what is discussed with people outside of the group and we will ask the other group members the same thing.

Your son may want to discuss tobacco use or tobacco use prevention with you. He may also have questions or concerns about the images or concepts 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.**

If you or your son has 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.

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 your son provides in this study. The study records may be inspected by representatives of the Food and Drug Administration (FDA) and Chesapeake IRB, which is a group of people who review research to protect the rights and safety of research participants. Everything your son shares will be kept private to the extent allowable by law. This means that we will not share any information your son provides with anyone outside the study unless it is necessary to protect him, or if required by law. **We will not share with you information your son provides about his tobacco-related attitudes, beliefs and behaviors.**

The focus groups will be livestreamed; however, this video will not be recorded and will be utilized only for real-time observation. The focus group session may be audio recorded and transcribed for study-related purposes. Your son will be given an opportunity to opt out of being audio recorded at the beginning of the discussion. The report generated using the audio transcripts will not link your son's comments directly to him or include his full name, and no one outside of the researchers will know what your son said during the focus group. 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 focus group.

All of the information we collect, including anything your son says in the focus group 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 son's 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 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?

This study is completely voluntary. Your child can stop participating at any time. You and your son 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.

Your son does not have to answer any questions he doesn't want to. He will receive the \$40 incentive for his participation in the focus group session even if he 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

[Click here to email](#)

If you or your son has 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 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.**

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 Parental consent 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.