OMB# 0910-0674 Exp: 3/31/2016
RETAIN FOR YOUR RECORDS

PARENT/GUARDIAN NOTIFICATION OF RESEARCH

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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Arlington, VA 22201

On <<DATES>> students at <<SCHOOL>> will have the opportunity to participate in research being conducted on campus. The goal is to understand what youth think about different messages and ideas designed to prevent smokeless tobacco use. Students who participate in the research will receive $25 for their time. You are receiving this form because you are the parent or legal guardian of a child who is eligible to take part in this study and your son has agreed to participate.

Please read this document carefully. It contains important information about this research study. You can ask as many questions as you want. If there is any information that you do not understand, we will be happy to answer your questions. **Please contact the researchers if you have any questions or if you do not want your son to participate in the study. If you do not want your son to participate, you must contact the researchers within the next 24 hours. Contact information is listed on the last page of this document.**

Introduction: About this study
The goal of the study is to understand what youth think about different kinds of advertising 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 a smokeless tobacco prevention campaign. Male youth will participate in focus groups to provide information that we will use to create a campaign to reduce youth tobacco use. We will collect their thoughts and opinions about marketing materials that may help prevent other youth from using tobacco. We are working with two research partners, Fors Marsh Group and the Michael Cohen Group, to do this. We plan to hold twenty-four focus groups with male youth 12 to 17 years of age in different locations.

Procedure: What will my son do during this study?
Your son has been invited to take part in a focus group that will take place at his school during the regular school day. Focus groups are a form of research used to gather opinions on a specific topic. Your son will be asked to share his thoughts with a trained interviewer and engage in a discussion with other group members (also students). Discussions will focus on ideas to be used in a smokeless tobacco prevention campaign. The focus group will take about 90 minutes.

There will be observers in the room during the group. They will take notes and listen, but they will not ask your son or the group any questions. Only a trained interviewer will be talking with your son.

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 ideas, images, and messages may prevent youth tobacco use.

Token of appreciation: Will my son be paid for being in this study?
Your son will receive $25 as a token of our thanks for taking part in the focus group. 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 $25 even if he chooses not to answer some questions.

Anticipated Risks: Could anything bad happen to my son during this study?
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 contacted and notified as to the extent of the breach, any damages incurred, and future potential risks; contact information for additional inquiries will also be provided.

Because this is a group session, people may share private thoughts that they would not want shared with others outside the group. We will ask your son to respect everyone's privacy by not sharing what is discussed with anyone outside of the group. We will ask the other group members to do the same.

Your son may want to discuss tobacco use or tobacco prevention with you. He may also have questions or concerns about the images or ideas 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 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?
Everything your son says 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.

In some cases, the focus groups may be live streamed so that researchers who cannot attend in person may observe the groups. Live streaming is a method of viewing the focus group remotely via the internet without recording it - similar to Skype or FaceTime. This video will not be recorded and will be used only for real-time observation. Your son will be told at the start of the focus group if the discussion is being live streamed. The focus group will be audio recorded and transcribed for research purposes. Your son can opt-out of being audio recorded at the start of the session. The audio tapes will be destroyed once the focus groups have been transcribed. No one outside of the focus group members and researchers will know what your son said during the discussions. We will not disclose your son's identity in any report or presentation.

Only the focus group interviewer, the staff from Sensis advertising agency, and researchers from Fors Marsh Group and the Michael Cohen Group will have access to your son's responses. Staff from the Food and Drug Administration (FDA) or Chesapeake IRB, which is a group of people who review research to protect the rights and safety of research participants, may also look at study records. Your son's responses will not be linked back to his full name or other personal information, meaning that no one outside of the researchers will know what he said during the focus group. 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. However, if he indicates a direct threat of harm to himself or others, we reserve the right to take necessary action out of concern for his welfare and the welfare of others. **FDA does not encourage the use or sale of tobacco products. 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.
All of the information we collect, including anything your son says 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 your son like age and race but we will not collect any information that could identify your son, like his 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 son's 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 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 focus group 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 $25 incentive for his participation in the focus group session even if he chooses not to answer some questions.

If you or your son choose not to participate at any time by contacting Kara Marsh of Fors Marsh Group at 571-858-3757 or by emailing a study representative at pi@forsmarshgroup.com.

Research Questions and Contacts: Whom do I call if my son or I have questions?
If you have any questions about this study, please call Kara Marsh of Fors Marsh Group at 571-858-3757 or by emailing a study representative at pi@forsmarshgroup.com.

If you or your son has any questions or complaints about his 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:

IMPORTANT:

If you do not want your son to participate, you must contact:

Kara Marsh, Fors Marsh Group
Phone: 571-858-3757
Email: pi@forsmarshgroup.com

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 Opt-out 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 PRAStaff@fda.hhs.gov.