

YOUTH ASSENT FORM AGES 12 – 17

TITLE OF INFORMATION COLLECTION: The Real Cost Smokeless: Wave 2 In-depth Interviews Designed to Prevent Rural Youth Tobacco Use

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

Principal Investigator: Brian Griepentrog, PhD

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You are being asked to take part in this research study about 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 local trends, lifestyles, and health-related behaviors to help develop ads that are designed to prevent smokeless tobacco use.

FCB New York 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 a research partner, Fors Marsh Group. We plan to conduct research in schools around the country with male youth 12 to 17 years of age (who will not turn 18 by the end of this week).

What will I do during this study?

Study staff will tell you when and where your assigned in-school interview is scheduled. During the interview, you will be asked some questions about you, such as what you like to do in your free time, your friends, and school. There will also be some questions about smokeless tobacco. The interview will last up to 90 minutes.

Interviews will take place during school hours on school premises. There will be observers in the room during the interview. They will take notes and listen, but they will not ask you any questions. Only a trained interviewer will be talking with you. The interview will be audio recorded and transcribed for reporting purposes. The audio tapes will be destroyed once the interviews have been transcribed.

What good comes from my participation?

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

What will I get for being in this study?

There is no compensation for participating in this study.

Could anything bad happen to me during this study?

The risks for taking part in the study are low. 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 interview, you can ask the interviewer or other representatives from Fors Marsh Group. You can also talk to your parent(s) or guardian(s) or a teacher or school counselor. If you have any questions about this study, you may call Brian Griepentrog 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?

Interviews will take place in a private area whereby any conversation will not be overheard by others outside of the interview. 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. Interview responses will not be shared with your parent(s) or 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. It is illegal in all states for adolescents under 18 to buy tobacco.

All of the information we collect, including all of your interview responses and data collected during screening, will be de-identified (your name or personal information will be removed) within one week of his interview and will be kept for 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, and you will not be re-contacted for this study. 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.

Who do I contact if I have questions about the study?

If you have questions or concerns about the study, you can contact:

Brian Griepentrog, Fors Marsh Group

571-858-3757

pi@forsmarshgroup.com

If you have questions about your rights as a research participant, please contact Chesapeake IRB by email at adviser@chesapeakeirb.com or by telephone toll free at 877-992-4724 and reference Pro00021668. 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.

Initials

Date

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.