PARENT/GUARDIAN OPT-OUT OF RESEARCH FORM

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, Ph.D.**

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On <<DATES>> students at <<SCHOOL>> will have the opportunity to participate in research being conducted on campus. The goal of this study is to gain insight around youth's local trends, lifestyles, and health-related behaviors to help develop advertisements that are designed to prevent smokeless tobacco use.

Please read this form carefully. It contains important information about this research study. 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.

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.

About this study
The goal of this study is gain insight around youth's local trends, lifestyles, and health-related behaviors to help develop advertisements that are designed to reduce youth tobacco use.

FCB New York is an advertising company partnering with the U.S. Food and Drug Administration (FDA) Center for Tobacco Products (CTP) to create a campaign. We would like your son's thoughts to help us create ads to prevent teens like your son from using tobacco. We are working with a research partner, Fors Marsh Group. We plan to conduct interviews 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 my son do during this study?
Your son has been invited to take part in one-on-one in-depth interviews. Interviews are a form of research used to gather opinions on a specific topic. Your son will be asked to share his typical habits, activities, preferences, and perceptions of daily life, as well as his attitudes and beliefs regarding tobacco use. The interview will take 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 your son any questions. Only a trained interviewer will be talking with your son. 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 this study?
There is no direct benefit to you or your son. However, your son's insight will help us decide what types of

advertisements may prevent youth tobacco use.

What will my son get for being in this study?
There is no compensation for participating in this study.

Anticipated Risks: Could anything bad happen to my son during this study?
The risks for taking part in the study are low. Your son may want to discuss tobacco use or tobacco prevention with you. If your son becomes upset or wants to stop participating, **he may stop participating in this study at any time.**

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 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 or your son have any questions about this research study, you may call Brian Griepentrog 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?
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 son's responses. Your son's name and other personal information will not be linked to your responses and you or your son will not be re-contacted for this study. A code will be used instead of names. We will be very careful to only let people working on the study have access to the responses your son provides, which will not be linked back to any personal information that can be used to identify him. Everything your son shares will be kept private to the extent allowed by law. This means that we will not share any information your son provides with anyone outside the study unless it is required to protect him, or if required by law. The Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) and Chesapeake IRB may have access to this study data.

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.

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, and it is illegal in all states for adolescents under 18 to buy tobacco.

All of the information we collect, including all of your son's responses and data collected during screening, will be de-identified 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 son's identity in any report or presentation. Results may also be used in future research or shared 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 interview at any time. No matter what your and your son's decision, there will be no penalty or loss of benefits to him. 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. The study is for research purposes

only. The only alternative is not to participate in the study. You and your son will be told about any new information found during the study that may affect whether your son wants to continue to take part. The investigator or the FDA may stop your son's participation at any time if it is in his best interest or the study is ended.

IMPORTANT:

If you do not want your son to participate, you must contact within 24 hours:

Brian Griepentrog, Fors Marsh Group
Phone: 571-858-3757
Email: 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. Please keep this form for your records. If you would like an additional blank copy of this form, you can email Brian Griepentrog at 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.