PARENT/GUARDIAN INFORMED PERMISSION FORM

TITLE OF INFORMATION COLLECTION: The Real Cost Smokeless: Wave 2 Focus Group Study of Reactions to Creative Advertising Concepts 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.**
Telephone:	**571-858-3757 (24 Hours)**
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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 understand what youth think about campaign materials that are designed to prevent smokeless tobacco use.

You are receiving this letter because you are the parent or legal guardian of a child who is eligible to take part in this study. Your son has agreed to participate, but your permission is required for him to do so.

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. **You must sign and date this form and have your son return it to study staff at his school before he can take part in the study.**

Introduction: About this study
The goal of this study is to understand what youth think about campaign materials meant 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 focus groups 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).

Procedure: What will my son do during this study?
Your son has been invited to take part in focus groups. Focus groups are a form of research used to gather opinions on a specific topic. Your son will be asked to share his thoughts on smokeless tobacco and may be asked to view and provide feedback on campaign materials designed to prevent teens from using smokeless tobacco. The focus group will take about 90 minutes.

Focus groups will take place during school hours on school premises. 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. Focus groups will be audio recorded.

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 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.

Could anything bad happen to my son during this study?
The risks for taking part in the study are low. Some of the images he sees during the study may be graphic or disturbing. Your son may want to discuss tobacco use or tobacco prevention with you. He may also have questions or concerns about the images or videos 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** and will still receive the incentive even if he drops out of the 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 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?
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 his 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 let only 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 this focus group and will be kept for at least 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 focus group at any time. No matter what your or 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.

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 the 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 a copy of 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.

PLEASE CHECK ONE OF THE BOXES AND SIGN BELOW.

☐ **Yes, I agree to allow 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 to allow 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.**

_____ _____

Signature *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 Parental Informed Permission 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.