OMB# 0910-0796 Exp. 6/30/2018

INFORMED CONSENT FORM

TITLE OF INFORMATION COLLECTION: Point-of-Sale Creative Concept Testing – Focus Groups with Current Adult Smokers

Sponsor:	**The Food and Drug Administration's (FDA) Center for Tobacco Products (CTP)**
Principal Investigator:	**Sarah Evans, PhD**
Telephone:	**571-858-3757 (24 Hours)**
Address:	**Fors Marsh Group, LLC (FWA00011194)** **1010 N. Glebe Road** **Suite 510** **Arlington, VA 22201**

You are being asked to take part in this study because you indicated you smoke cigarettes and have stopped smoking cigarettes for more than one day during the past 12 months because you were trying to quit smoking. 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 research team 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 complete and sign this form before you can take part in the study. You will receive a copy for your records.

About this study
The goal of this study is to understand reactions to different ideas for advertisements.

FCB Garfinkel is an advertising company partnering with the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) to create an advertising campaign. We would like your thoughts and opinions about smoking cigarettes and various advertising ideas. We are working with our research partner, Fors Marsh Group, and we plan to hold eight focus groups in each of four locations with current cigarette smokers.

What will I do during this study?
The research team will tell you when and where your assigned focus group is scheduled. During the session, you will be asked to share your thoughts with the moderator about advertisement ideas related to quitting smoking. The focus group will last about 90 minutes. There are no costs associated with your participation in this study. You do not have to answer any questions that you don't want to.

Other people from the FDA or FCB Garfinkel will be observing the session, either in-person or via live streaming. They will take notes and listen, but they won't bother you. You will only be talking to the moderator and a small group of other participants.

Study Benefits: What good comes from my participation?
There is no direct benefit to you. Your feedback will help us decide what ideas and messages may best motivate and encourage people to quit smoking.

Will I be paid for being in this study?
You will receive $75 as a token of appreciation for your participation. A gift card that functions as a pre-paid debit card will be issued upon completion of the focus group. You will receive the gift card for your time even if you choose not to answer some questions during the discussion.

Anticipated Risks: Could anything bad happen to me during this study?
We will be very careful to only let people working on the study see your information. There is a small risk that others might find out what you say, despite all of our best efforts. In the case of a breach of confidentiality, appropriate steps will be taken to notify participants. **Remember that you can stop participating in this study at any time.**

Privacy: Who will see the results of this study?
Everything you say during the focus group can be heard by the research team.

The focus group will be audio recorded and transcribed. It may also be livestreamed so that other researchers who could not travel can watch remotely. You will be told at the start of the focus group whether it is being livestreamed. By signing this form, you consent to being audio recorded and livestreamed during the focus group.

Your name and other personal information will not be linked to your responses. This means that no one outside of the research team will be able to link what you said back to you. Everything you share will be kept private to the extent allowed by law. This means that we will not share anything you provide with anyone outside the study unless it is required to protect you, or if required by law. However, if you show a direct threat of harm to yourself or others, we have the right to take action out of concern for you and concern for others.

All of the information we collect, including anything you say during the focus group, information collected during screening, 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 you, like your age and race, but we will **not** collect any information that could identify you personally. 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.

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 can decide not to participate at any time by contacting Sarah Evans of Fors Marsh Group at 571-858-3757.

You also do not have to answer any questions that you do not want to. You will receive the $75 gift card for your time in the focus group even if you choose 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:
Sarah Evans, Fors Marsh Group
571-858-3757
pi@forsmarshgroup.com

☐ **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.**

The research team will provide you a copy of this form for your records.

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 Informed 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 PRAStaff@fda.hhs.gov.