OMB# 0910-0810 Exp. 11/30/2018

INFORMED CONSENT FORM

TITLE OF INFORMATION COLLECTION:
Point-of-Sale Campaign: Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Encourage Adult Smokers to Quit Smoking

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 research 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.

If you have any questions about the study you may contact the research staff at Fors Marsh Group at 571-858-3757 or by email at PI@forsmarshgroup.com. 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 reactions to different ideas for advertisements.

FCB New York is an advertising company contracted by 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 various advertising ideas. We are working with our research partner, Fors Marsh Group, and we plan to survey up to 2,844 current cigarette smokers across the United States.

What will I do during this study?
During the survey, you will be asked some questions about smoking cigarettes, and about quitting smoking; some participants will be asked to view and provide feedback on advertisements related to quitting smoking. The survey will last about 20 minutes.

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 make another attempt to quit smoking.

Will I be paid for being in this study?
You will receive an e-reward which means points will be added to your account through the online panel provider which is equal to approximately $1.50 for participating in this study. You will receive your e-reward when you complete the survey even if you choose to not answer some questions.

Anticipated Risks: 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 about the study you may contact the research staff at Fors Marsh Group at 571-858-3757 or by email at PI@forsmarshgroup.com. **Remember that you can stop being in this study at any time.**

If you are thinking about quitting, you are advised to speak with your healthcare provider for more information on ways to quit tobacco that could work for you.

Privacy: Who will see the results of this study?
Only the authorized research staff will have access to your 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. Some demographic information, like your age, gender, and race/ethnicity, will be gathered, but no personal information, like your name, will be collected. Your identity 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. 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.

All of the information we collect, including all of your survey responses and data collected during screening, 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 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 also do not have to answer any questions that you do not want to. There is no penalty or loss of benefits.

Getting Answers to Your Questions or Concerns about the Study
You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study).

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

If you have questions about your rights as a research participant, please contact FDA IRB RIHSC (RIHSC@fda.hhs.gov), and reference IRB #_____. An IRB is a group of people who review research studies to protect the rights and safety of research participants.

You may also contact Chesapeake IRB for questions about your rights as a research participant by contacting:

- By mail:
  Study Subject Adviser
  Chesapeake IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@chesapeakeirb.com

Please use the following number when contacting the Chesapeake IRB Study Subject Adviser: Pro00018741

If you would like a copy of this form, please click here to save or print a 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.**

Submit

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 3 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.