OMB Control # 0910-0810
Exp. Date: 11/30/2018

General Market Campaign: Wave 3 Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use

YOUTH ASSENT FORM

Please read this form carefully. 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 submit this form before you can take part in the study.**

Introduction: About this study
The purpose of this research study is to determine how well ads work to prevent youth from using tobacco. FCB is an advertising company partnering with the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products (CTP). This study will test draft versions of ads to decide if they are understood. We are interested in hearing your thoughts about the ads.

Your Role in This Study: What will I do during this study?
You will be one of a group of up to 1,292 youth in an online study. The study will take place from [DATE RANGE]. The study will not take longer than 10 minutes. During that time, you will answer questions on the screen about the messages and ideas you are shown.

Privacy: Who will see my answers during this study?
We will take care to protect your privacy. The study will take place on a secure website that is password protected. The site will not display your personal information. Your answers will be kept private to the extent allowable by law. Some personal information will be gathered, but no personal information will be kept after screening. This means that your answers will not be connected to your name. No one will know what answers you gave us. Your parents or guardians will not see your answers, but they will be provided with a blank copy of the questions you will be asked if they request one.

If you agree to participate, some information collected during screening may become part of the final data set, and all data will be kept for three years and stored on a password protected computer or in a locked cabinet. After that, all data will be destroyed either by secure shredding or permanent deletion.

Information you share about your tobacco-related attitudes, beliefs and behaviors will not be shared with anyone, including your parent(s)/guardian(s).

Data from this study may appear in professional journals or at scientific conferences. We will not disclose your identity in any report or presentation. Data from this study may also be used in the future, or shared with other researchers. However, anyone who looks at this data will not have your name or any other information about you.

Will I be paid for being in this study?
Everyone who participates in this study will receive a $20 eGift card.

Anticipated Benefits: What good will come from my participation?
This study is not expected to directly benefit you. However, your feedback will help us decide which advertisements we developed.

Anticipated Risks: Could anything bad happen to me during this study?
We will take care to protect the information you provide. However, as with all studies, there is a chance that privacy could be broken as a result of an accidental error or a security breach. Some of the images you may see during this study may be graphic or disturbing. You should talk to your parents, guardians, or school counselors about any concerns you have about how these images made you feel or about any questions or concerns you have about smoking.

Participation and Withdrawal: Do I have to be in this study? What if I want to stop participating?
This study is completely voluntary. You do not have to answer any questions you do not want to. You will receive the $20 eGift card for participating in the study even if you choose to skip questions.

Research Questions and Contacts: Whom do I call if I have questions now or later?
If you have any questions about this research study, you may call David Cortés at FCB (212-885-3743). If you have questions about your rights as a research participant, please contact RIHSC at 301-796-9605, or at RIHSC@fda.hhs.gov and reference RIHSC #16-034T. The Research Involving Human Subjects Committee (RIHSC) at the Food and Drug Administration has reviewed this research. RIHSC is an institutional review board, a group of people who are responsible for assuring that the rights of participants in research are protected. The RIHSC may review the records of your participation in this research to assure that proper procedures were followed.

○ **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.**

Print

Please print a copy of this form for your records.

Submit

Paperwork Reduction Act Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. 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 PRAStaff@fda.hhs.gov.