

# ONLINE QUANTITATIVE STUDY OF YOUTH REACTIONS TO ROUGH-CUT ADVERTISING DESIGNED TO PREVENT YOUTH TOBACCO USE AMONG GENERAL MARKET YOUTH (WAVE 2)

## INFORMED ASSENT FORM

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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 study is to determine whether advertisements designed to prevent youth from using tobacco provide an understandable and engaging message about the harms of tobacco use.

FCB is an advertising company partnering with the U.S. Food and Drug Administration's Center for Tobacco Products (CTP) to hold an online copy testing study with youth nationwide. The study involves showing draft versions (i.e., "rough-cuts") of television advertisements to consumers to determine if the messages are understood. Youth participating in this study will view rough-cut advertisements we have developed to prevent youth from using tobacco. We are interested in hearing your thoughts and opinions about these advertisements. We will use your feedback to determine which advertisements provide an understandable and engaging message about the harms of tobacco use.

### **Your Role in This Study: What will I do during this study?**

You will be one of a group of 1,800 youth participating in an online study. The study will take place from [DATE RANGE] on a secure website that is password protected. The study will take no longer than 10 minutes. During that time, you will answer questions on the screen about the messages and ideas you are shown. Your answers will be kept private to the extent allowable by law.

### **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 and will not display your personal information. Your answers will be kept private to the extent allowable by law. That means we will not share your answers with anyone outside the study unless it is necessary to protect you, or if it is required by law. Although some personal information will be gathered (e.g., gender, age, race, thoughts, opinions and reactions to messages and ideas designed to prevent youth from using tobacco) no personal identifiers (e.g. full name and email address) will be maintained after screening. This means that after you agree to participate, your answers to our questions will not be connected to your name or contact information. No one will know what answers you gave us.

If you agree to participate, some data collected during screening may become part of the final data set, and all data collected during screening and during the study 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 of electronic information.

We will not share information with anyone outside of the study unless it is necessary to protect you, or if it is required by law. **Information you share about your tobacco-related attitudes, beliefs and behaviors will not be shared with others, 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 future research or shared with other researchers. However, anyone who looks at this data will not have your name or any other information that could reveal your identity.

**Token of Appreciation: Will I be paid for being in this study?**

Everyone who participates in this study will receive a \$20 eGift card as a token of appreciation for participating in the study.

**Anticipated Benefits: What good will come from my participation?**

This study is not expected to directly benefit you. However, your feedback will help us determine whether the rough-cut advertisements we developed provide an understandable and engaging message about the harms of tobacco use.

**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 possibly disturbing, but within the context of tobacco prevention. 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.

If you have any questions about this research study, you may call Charlie Cook at FCB (212-885-2987) or Tesfa Alexander at CTP (301-796-9335). **Remember that you can stop participating in this study at any time.**

**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 participating at any time. You do not have to answer any questions you do not want to. You will receive the \$20 token of appreciation for participating in the study even if you choose to not answer some 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 Charlie Cook at FCB (212-885-2987) or Tesfa Alexander at CTP (301-796-9335). If you have questions about your rights as a research participant, please contact Dr. Bruno Anthony, IRB chair (410-371-7548) and reference IRB # \_\_\_\_\_.

- 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: The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete the Informed 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 [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).**