

**INFORMED CONSENT FOR
ONLINE QUANTITATIVE STUDY OF YOUTH REACTIONS TO
TOBACCO PREVENTION CAMPAIGN MESSAGING:**

PARENTAL CONSENT

OMB No: 0910-0674

Expiration Date: 03/31/2016

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 5 minutes per response (the time estimated to sign this letter and submit it to FDA). You can send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRStaff@fda.hhs.gov.

Please read this form carefully. You can ask as many questions as you want. If there is any information you do not understand, researchers will be happy to explain it to you. **You must submit this form before your child can take part in the study.**

Introduction: About this study

The **purpose** of this study is to determine whether rough-cut advertisements designed to prevent youth from using tobacco provide an understandable and engaging message about the harms of tobacco use.

DraftFCB is an advertising company partnering with the U.S. Food and Drug Administration's Center for Tobacco Products (CTP) to conduct an online copy test with youth nationwide. Youth participating in this study will view rough-cut advertisements we have developed to help prevent youth from using tobacco. We will collect their thoughts and opinions about these advertisements. We will use their feedback to determine which advertisements provide an understandable and engaging message about the harms of tobacco use.

Procedures: What will my child do during this study?

Your child will be part of a group of 1,575 youth participating in an online study. The study will take place from October 16, 2013 to October 24, 2013 on a secure website that is password protected. The study will take no longer than 10 minutes. During that time, your child will answer questions on the screen about the advertisements he/she is shown. Your child's answers will be kept private to the extent allowable by law.

This study is completely voluntary. You can choose whether or not to give permission for your child to take part in this study. Your child can also choose whether or not to take part in or complete this study.

Privacy: Who will be able to see what my child writes or posts during this study?

We will take care to protect your child's privacy. This study will take place on a secure website that is password protected and will not display your child's personal information. Your child's answers will be kept private to the extent allowable by law. That means we will not share your

child's answers with anyone outside the study unless it is necessary to protect them, 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, address, social security number) will be collected during the study or maintained.

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 your child, or if it is required by law. **Information your child shares about their tobacco-related attitudes, beliefs and behaviors will not be shared with others, including you.**

Data from this study may appear in professional journals or at scientific conferences. We will not disclose your child's 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 child's name or any other information that could reveal his/her identity.

Token of appreciation: Will my child be paid for being in this study?

The amount of the incentive for participation is a \$20 eGift card. Participants who are age 16 and older will receive the entire \$20 incentive. Participants who are under age 16 will receive a split incentive (i.e., the youth participant will receive a \$10 eGift card and their parent or guardian will receive another \$10 eGift card).

Study Benefits: What good will come from this study?

This study is not expected to directly benefit you or your child. However, your child's 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 or my child during this study?

We will take care to protect the information your child provides. However, as with all studies, there is a chance that confidentiality could be broken as a result of an accidental error or a security breach.

Your child may want to discuss tobacco use or tobacco use prevention with you. Your child may also have questions or concerns about the images or concepts he/she sees during this study. If your child becomes upset or wants to stop participating, **your child may stop participating in this study at any time.**

All information will be kept confidential and will not be shared with anyone outside this study unless it is necessary to protect you or your child, or if required by law. If you have any questions about this study, you may call Charlie Cook at DraftFCB (212-885-2987) or Tesfa Alexander at CTP (301-796-9335).

Participation and Withdrawal: Does my child have to be in this study? What if he/she changes her mind?

This study is completely voluntary. You and your child are allowed to stop participating at any time. Your child does not have to answer any questions he/she does not want to. Your child will receive the \$25 incentive for participating in the study even if he/she chooses to not answer some questions.

Research Questions and Contacts: Who do I call if I have or my child has questions?

If you have any questions about this study, you may call Charlie Cook at DraftFCB (212-885-2987) or Tesfa Alexander at CTP (301-796-9335).

- Yes, I agree for my child 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 for my child 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.**



Please print and/or save a copy of this form for your records.



Date

Date