

**INFORMED CONSENT FOR ONLINE QUALITATIVE STUDY OF
YOUTH REACTIONS TO STRATEGIC CONCEPTS DESIGNED TO
PREVENT YOUTH TOBACCO USE**

June 26, 2013

RIHSC #:

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 check the box at the bottom of this form before your child can take part in the study.**

Introduction: About this study

The **purpose** of this study is to understand what youth think about different kinds of messages and ideas designed to prevent youth from using tobacco.

DraftFCB is an advertising company partnering with the U.S. Food and Drug Administration’s Center for Tobacco Products (CTP) to conduct an online forum with youth nationwide. Youth participating in this study will view marketing ideas we have developed to help prevent youth from using tobacco. We will collect their thoughts and opinions about those images and concepts. We will use their feedback to develop advertisements and messages that may help prevent other youth from beginning to use tobacco products.

Procedures: What will my child do during this study?

Your child will be part of a group of 15 youth participating in an online forum. The forum will take place on a secure website that is password protected. Your child will create a non-personal screen name that is not their real name. This means other youth in the forum will not be able to tie your child’s comments directly back to them. Everything your child writes will be kept private to the extent allowable by law.

The study will take place over a 3 day period. During this time, we will ask your child to log in to the site at least twice a day but no more than four times a day to complete different tasks, although he/she may access the site at any time during the day as he/she wish. Your child will need no more than 40 minutes to complete all of the assigned activities on any given day; however, the activities are not timed and he/she may spend as much time on the site as he/she wishes to. Your child’s total participation time for the study is not expected to exceed 120 minutes (2 hours). The group leader will post questions about images, ideas, and tobacco use prevention messages. Your child and the other participants will type in answers to the questions. He/she will also be able to comment on other peoples’ answers.

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. Your child is allowed to skip any questions or posts that he/she does not want to answer.

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

Everything your child writes can be seen by the other 14 participants, the online moderator, the study investigators, and FDA quality monitors. All participants will be asked to respect the privacy of the other focus group members. Everyone will be asked not to discuss/reveal any information they learn about other participants during the study.

This forum will take place on a secure website that is password protected. Participants will create non-personal screen names that are not their real names. All posts will be kept private to the extent allowable by law. This means we will not share information with anyone outside of the study unless it is necessary to protect your child, or if required by law. The group leader will not know any information that may identify your child outside of the online forum but will monitor all of the information and posts on this website. This person will work with the research team and will instruct participants to not share any private, personally identifiable, or inappropriate information. Posts considered private or inappropriate will be promptly removed from the forum by the group leader.

The information your child provides at the time of screening may contain sensitive information (e.g. smoking status). If we find out that your child uses tobacco, we will not share this information with you. The website will be ‘live’ for a period of 2 weeks and, after that, will be taken offline. All information, including anything your child wrote in the online forum and data collected during screening, will be kept for a period of three years and stored on a password-protected computer or a locked cabinet. After three years, all of the collected data will be destroyed either by the secure shredding of documents or the permanent deletion of electronic information. Information from this study may be published in professional journals or at scientific conferences, but your child’s confidentiality will be respected and his/her identity will not be revealed in any report or presentation. The investigators may also use data from this study in future research and/or share data with other researchers. Other investigators will NOT have your name or any identifying information.

Reimbursement: Will my child be paid for being in this study?

Everyone who takes part in this study will receive \$20 for each day of involvement. The maximum amount you can earn for participating in the study is \$60. The incentive will be paid directly to you through an eGift card sent to your child’s email address. The eGift card can be used online at any merchants that accept Visa or MasterCard.

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 decide what ideas, images and messages may prevent youth tobacco use.

Anticipated Risks: Could anything bad happen to my child during this study?

We will take precautions to minimize the potential risks of participating in this study. However, as with all research, there is a chance that confidentiality could be compromised. For example:

- Although everyone will be asked not to discuss/reveal any information other participants shared during the study, it is important to understand that other participants may not keep all information private and confidential.

- Despite the best efforts of the research team to maintain the confidentiality of information collected during the study, a privacy/data breach may occur from inadvertent human error or as a result of hacking.
- Participants may inadvertently share private, personally identifiable, or inappropriate information. The group leader will monitor the online discussion and promptly remove posts that contain such information; however, it is important to understand that other participants could see the information prior to its removal.

Breaches of confidentiality may put participants at risk of identity theft, embarrassment, or damage to reputation.

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 private to the fullest extent allowable by law and will only be shared if it is necessary to protect your child, or if required by law. If you have any questions about this study, you may call Tanya White at DraftFCB (212-885-2987).

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 \$20 incentive for each day he/she participates 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 Tanya White at DraftFCB (212-885-2987) or [click here](#) to contact a study representative.

Yes, I agree for my child to take part in this study. I have read, understand, and had time to consider all of the information above. I have no more questions about this study at this time.

No, I do not agree for my child to take part in this study. I have read, understand, and had time to consider all of the information above. I have no more questions about this study at this time.

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OMB No: 0910-0674

Expiration Date: 03/31/2016

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