

INFORMED ASSENT 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 anything you do not understand, we will be happy to answer your questions. **You must check the box at the bottom of this form before you 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 hold an online forum with youth nationwide. Youth participating in this study will view marketing ideas we have developed to prevent youth from using tobacco. We are interested in hearing your thoughts and opinions about these ideas. We will use your feedback to develop advertisements and messages that may prevent other youth from beginning to use tobacco products.

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

You will be one of a group of 15 youth participating in an online forum. The forum will take place on a secure website that is password protected. You will create a non-personal screen name that is not your real name. This means the other youth in the forum will not be able to tie your comments directly to you. Everything you write will be kept private to the extent allowable by law.

The study will take place over a 3 day period. You will be asked to log in to the site at least twice a day but no more than four times a day to complete different tasks, but may access the site at any time during the day you wish. You 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 you may spend as much time on the site as you'd like. Your 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. You and the other participants will type in answers to the questions. You will also be able to comment on other peoples' answers.

Privacy: Who will see my answers during this study?

Everything you write can be seen by the other 14 participants, the online moderator, the study investigator(s), 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.

The forum will take place on a secure website that is password protected. You will create a non-personal screen name that is not your real name. Everything you write will be kept private to the extent allowable by law. This means we will not share anything you write with anyone outside the study unless it is necessary to protect you, or if required by law. The group leader will not know any information that may identify you 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 containing private or inappropriate information will be promptly removed from the forum by the group leader.

The information you provide at the time of screening may contain sensitive information (e.g. smoking status). If we find out that you use tobacco, we will **not** share this information with your parent(s)/guardian(s). The website will be ‘live’ for a period of 2 weeks and, after that, will be taken offline. All information, including anything you 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 confidentiality will be respected and your identity will not be revealed in any report or presentation.

Reimbursement for Participation: Will I be paid for being in this study?

Everyone who participates 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 email address. The eGift card can be used online at any merchants that accept Visa or MasterCard.

Anticipated Benefits: What good comes from my participation?

This study is not expected to directly benefit you. However, your feedback will help us decide what ideas, images or messages may prevent youth tobacco use.

Anticipated Risks: Could anything bad happen to me 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.

You may also have questions about tobacco use or tobacco use prevention before, during or after this study. You can ask the group leader any questions you have about this forum or about anything you see on the website. You can also talk to your parents or a teacher or school counselor. **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 can revoke your consent to participate at any time by contacting Tanya White at DraftFCB (212-885-2987).

You do not have to answer any questions you do not want to. You will receive the \$20 incentive for each day you participate 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 Tanya White at DraftFCB (212-885-2987) or [click here](#) to contact a study representative.

Yes, I would like to participate 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 would not like to participate 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.

Full Name: _____

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Please print or save a copy of your records.

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OMB No: 0910-0674

Expiration Date: 03/31/2016

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