

INFORMED CONSENT FOR CREATIVE CONCEPT RESEARCH YOUTH ASSENT

TITLE OF INFORMATION COLLECTION: Focus Group Study of Youth Reactions to Creative Advertising Concepts Designed to Reduce Tobacco Use

DATE/VERSION:

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 sign 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 reduce youth tobacco use.

DraftFCB is an advertising company partnering with the U.S. Food and Drug Administration's Center for Tobacco Products to hold focus groups 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 six (6) youth participating in an in-person focus group. The focus group will take place in a research facility.

The study will take place on [DATE] at [RESEARCH FACILITY] for 90 minutes. The group leader will ask questions about images, ideas and tobacco use prevention messages. You and the other participants will be asked to share your thoughts and opinions in response to these questions.

Privacy: Who will see the information I provide during this study?

Everything you say during the focus group will be heard by the other five (5) participants, the group leader, and members of the research team who will be observing the discussion behind a one-way mirror. All participants will be asked to respect the privacy of the other focus group members. Everyone will be asked to not discuss/reveal anything said during the discussion.

Focus group discussions may be audiotaped and transcribed for reporting purposes. The report generated using this information will not link your comments directly to you or include your full name, and no one outside of the focus group participants and researchers will know what you said during the discussions. Only your first name will be used during the check-in process and during the discussions; your full name will not be shared with the group leader or other participants. The group leader will also instruct participants to not share any private, personally

identifiable, or inappropriate information during the discussion. Comments containing private or personally identifiable information will be removed from the transcripts.

The audio files and transcripts will be stored on a password-protected computer and/or in locked cabinets that are only accessed by the research team. 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 focus group discussion.

All information, including anything you say in the focus group 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.

All information you provide will be kept private to the extent allowable by law. This means that 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 your parent(s)/guardian(s).**

Anonymous data from this study may be published in professional journals or at scientific conferences, but no individual participant will be identified or linked to the results. We will not disclose your identity 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 for Participation: Will I be paid for being in this study?

Everyone who participates in this study will receive a \$50 gift card.

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.
- 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.
- Although participants will be reminded to not share any private, personally identifiable, or inappropriate information, they may inadvertently share such information. The

information will be removed from the audio transcripts; however, it is important to understand that the other five (5) focus group participants could still hear and react to the information that was shared.

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 focus group. You can also talk to your parent(s)/guardian(s) or a teacher or school counselor.

If you have any questions about this research study, you may call Tanya White at DraftFCB (212-885-2987). **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 \$50 incentive for your participation 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).

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Paperwork Reduction Act Statement: The public reporting burden for this collection of information has been estimated to average 1.5 hours per response. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRAStaff@fda.hhs.gov

I have read, understand, and had time to consider all of the information above. My questions have been answered and I would like to participate in this study.

Printed Name of Youth Research Participant

Signature of Youth Participant

Date

Signature of Investigator/Witness

Date