

INFORMED CONSENT FOR CREATIVE CONCEPT RESEARCH PARENT CONSENT

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 any information you do not understand, researchers will be happy to explain it to you. **You must sign 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 reduce youth tobacco use.

DraftFCB is an advertising company partnering with the U.S. Food and Drug Administration's Center for Tobacco Products to conduct focus groups 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 one of a group of six (6) youths 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. Your child and the other participants will be asked to share their thoughts and opinions in response to these questions.

Privacy: Who will see the information my child provides during this study?

Everything your child says during the focus group can 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 child's comments directly to him/her or include his/her full name. No one outside of the focus group participants and researchers will know what your child said during the discussions. Only your child's first name will be used during the check-in process and during the discussions; his/her 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 your child said 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 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 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 child's 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 child's 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 a \$50 gift 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 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.
- 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.

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.**

If you have any questions about this research 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 my child changes her mind?

This study is completely voluntary. You and your child are allowed to stop participating at any time. You can revoke your consent for your child to participate at any time by contacting Tanya White at DraftFCB (212-885-2987).

Your child does not have to answer any questions he/she does not want to. Your child will receive the \$50 incentive for his/her participation in the study even if he/she chooses to not answer some questions.

Research Questions and Contacts: Whom do I call my child or I have questions?

If you have any questions about this 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 PRASStaff@fda.hhs.gov

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. I would like my child to take part in this study.

Printed Name of Youth Research Participant

Signature of Parent

Date

Signature of Investigator/Witness

Date