

WAVE 3 PHASE 1 QUALITATIVE RESEARCH: GENERAL MARKET AT-RISK YOUTH TOBACCO PREVENTION FOCUS GROUPS

PARENT CONSENT FORM

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.

FCB is an advertising company partnering with the U.S. Food and Drug Administration's Center for Tobacco Products (CTP) to conduct focus groups with youth nationwide. Youth participating in this study will view marketing ideas developed to help prevent youth from using tobacco. We will collect his/her thoughts and opinions about those images and concepts. We will use his/her feedback to develop advertisements and messages that may help prevent 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 youths participating in an in-person focus group at a research facility.

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

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

All participants will be asked to respect the privacy of the other focus group members. Everyone will be asked not to disclose 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 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. This means that after

your child agrees to participate, his/her answers will not be connected to his/her name or contact information. No one will know what answers your child gave us.

All personal information, including data collected during screening and the focus group discussion, will be destroyed three years after the completion of the study either by the shredding of documents or the permanent deletion of electronic information.

If your child agrees to participate, all 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.

All information your child provides 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 during the focus group discussions about his/her tobacco-related attitudes, beliefs and behaviors will not be shared with you.

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.

Will my child be paid for being in this study?

All of the youth who take part in this study will receive \$50 as a token of our appreciation for being in this study.

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 me or my child during this study?

The risks for taking part in this study are low. Some of the images your child may see during this study may be graphic or possibly disturbing to your child, but within the context of tobacco prevention. 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.**

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 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. You or 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 \$50

token of appreciation for participating 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 David Cortés at FCB (212-885-3743). If you have questions about your or your child’s rights as a research participant, please contact [INSERT IRB CHAIR NAME AND PHONE NUMBER], and reference IRB #_____.

I have read and understand 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

Paperwork Reduction Act Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete the Parent Consent Form (the time estimated to read, review, and complete). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRStaff@fda.hhs.gov.