

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

YOUTH ASSENT FORM

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 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 hold focus groups with youth across the United States. Youth in this study will view messages developed to prevent youth tobacco use. We want to hear your thoughts and opinions about these ideas.

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

You will participate in an in-person focus group with other youth 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. You will be asked to share your thoughts and opinions in response.

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

Participants will be asked to respect the privacy of the other focus group members. Everyone will be asked not to talk about anything that was said once the focus group is over.

Focus group discussions will be audio taped and turned into notes for reporting purposes. They may also be live streamed so that researchers who can't travel can watch the groups. Groups will not be video recorded.

The report we create using this information will not link your comments to you or include your full name. No one aside from other participants and researchers will know what you said during the discussions. Only your first name will be used during check-in and during the discussions. Your full name will not be shared with the group leader or other participants.

The audio files and notes will be stored on a password-protected computer and/or in locked cabinets. Only the research team will be able to access them. . Some personal information was gathered during the screening process, but none will be collected during the focus group.

All personal information will be destroyed 3 years after the study is over. It will be destroyed either by shredding the documents or permanently deleting electronic files.

Information you share about your tobacco-related attitudes, beliefs, and behaviors will not be shared with anyone, including your parent(s) or guardian(s).

Anonymous data from this study may be published in professional journals or at scientific conferences, but no participants will be identified or linked to the results. We will not reveal your identity in any report or presentation.

Will I be paid for being in this study?

Everyone who participates in this study will receive a \$50 pre-paid gift card for being in this study.

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 care to protect the information you provide. However, as with all studies, there is a chance that privacy could be broken because of an accidental error or a security breach. In the event a breach occurs, all participants will be contacted and notified as to the extent of the breach, any damages incurred, and future potential risks; contact information for additional inquiries will also be provided.

Some of the images you see during the study may be graphic or disturbing. The risks for taking part in the study are low. You can ask the group leader any questions you have about this focus group. 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 voluntary. You can stop at any time. You do not have to answer any questions you do not want to. You will receive the \$50 gift card even if you choose to stop.

Research Questions and Contacts: Whom do I call if I have questions now or later?

If you have any questions about the research study, call David Cortés at FCB (212-885-3743). If you have questions about your rights as a research participant, please contact [INSERT IRB CHAIR NAME AND PHONE NUMBER], and reference IRB # [REDACTED].

I have read and understand 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

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 Youth Assent 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.