

PARTICIPANT ASSENT FORM

TITLE OF INFORMATION COLLECTION:

Focus Group Study of Youth Reactions to Strategic and Creative Advertising Concepts
Designed to Prevent Youth Tobacco Use among Multicultural Youth

Sponsor: U.S. Food and Drug Administration's
Center for Tobacco Products

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Please read this form carefully.

You can ask as many questions as you want. If there is anything you do not understand, researchers can explain it to you. Any question you may have needs to be addressed before you sign this form. **Please sign this form in-person when you come to the focus group.**

Introduction: About this study

The purpose of this research is to understand teen culture and gain insight from teens to inform a tobacco prevention brand.

Rescue Social Change Group (Rescue SCG) is a health communications and research company. We are working with the U.S. Food and Drug Administration's Center for Tobacco Products to conduct focus groups with youth ages 12 to 17. We will use this information to develop a campaign to reduce youth tobacco use.

What will I do during this study?

You are invited to take part in an in-person focus group with no more than 12 participants. You can choose to take part in the study or not, regardless of what other students choose to do. You can choose to leave the focus group at any time. This will not affect your school standing.

The study will take place on _____ at your school. It will happen after school hours for 90 minutes. The group leaders will ask questions about teen culture or feedback regarding study materials. You and the other participants will be asked to share your opinions.

Who will see the information I provide during this study?

Everything you say during the focus group can be heard by the other teens, the group leader, research assistants, and FDA study monitors.

All participants will be asked to respect the privacy of the other teens. Everyone will be asked to

not share anything said during the focus group.

Focus group discussions may be audiotaped and transcribed. You can choose not to be audiotaped at the start of the session. The written notes will not be used to link your comments to you. No one beyond the other participants and the researchers will know what you said during the discussions. Your name will be used only during check-in. The group leader will ask participants not to share any private, personal, or inappropriate information. Comments containing this information will be removed from the notes.

The audio files and notes will be stored on a password-protected computer and/or in locked cabinets. Only research team members will have access to these items. We will collect some personal information such as gender, age, and race. We will not collect any data that can be used to identify you, such as your full name, address, or social security number.

All data, including anything you say in the focus group, will be kept for three years. It will be stored on a password-protected computer or in a locked cabinet. After three years, we will destroy all of the data by securely shredding and permanently deleting records.

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 attitudes, beliefs and behaviors will not be shared with others. This includes your parent(s)/guardian(s).**

Data from this study may appear in professional journals or at scientific conferences. We will not disclose your identity in any report or presentation.

Data from this study may be used in future research. We may share the data with other researchers. Anyone who looks at this data will not have your name or any other data that could reveal your identity.

Will I be paid for being in this study?

Everyone who takes part in this study will receive a token of appreciation of a \$25 non-retailer specific electronic gift card

You have been invited to participate in a focus group. But, if you do not arrive on time to the focus group location, you may be disqualified.

What good will come from this study?

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

Could anything bad happen to me during this study?

We will take care to protect the data you provide. However, as with all studies, there is a chance that privacy could be broken. For example:

- Everyone will be asked not to discuss anything other participants share during the study. However, other participants may not keep all information private.
- We will try our best to maintain the privacy of data collected during the study. Still, a breach could occur by accident or as a result of hacking.
- Teens will be reminded to not share any private, personally identifiable, or inappropriate

information. However, they may accidentally share such information. This data will be removed from the notes but other participants could still hear it.

If you have any questions about tobacco use or prevention, you can ask the group leader. You can also talk to your parent(s)/guardian(s), a teacher, or a school counselor.

Remember that you can leave the focus group at any time.

Do I have to be in this study? What if I want to drop out?

You can choose to take part in the study or not, regardless of what other students choose to do. You can choose to leave the focus group at any time. You do not have to answer any questions you do not want to. You will receive the \$25 gift card even if leave the focus group early or you choose to not answer some questions.

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

If you have any questions about this study, please contact the principal investigator or the study staff at the telephone number or email address listed on the first page of this form. If you have any concerns about this study, please contact:

- By mail:
Study Subject Adviser
Chesapeake IRB
6940 Columbia Gateway Drive, Suite 110
Columbia, MD 21046
- or call **toll free:** 877-992-4724
- or by **email:** adviser@chesapeakeirb.com

Please reference the following number when contacting the Study Subject Adviser:
Pro00009804.

An IRB is a group of people who review research studies to protect the rights and safety of research participants.

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 agree to take part in this study.

Printed Name of Youth Research Participant

Signature of Youth Research Participant

Date

Printed Name of Witness (Researcher)

Signature of Witness (Researcher)

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 Informed 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 PRASStaff@fda.hhs.gov.