

PARTICIPANT ASSENT FORM

TITLE OF INFORMATION COLLECTION: Multicultural Youth Tobacco Prevention Campaign: Pilot (Brand and Creative Concept Phase)

February 5, 2014

Institutional Review Board Protocol #: PBCC1

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 study is to understand teens' thoughts about tobacco prevention marketing.

Rescue Social Change Group (Rescue SCG) is a social marketing company. We are working with the U.S. Food and Drug Administration's Center for Tobacco Products to conduct focus groups with youth aged 12 to 17 in Atlanta, GA and Charlotte, NC. We will use this information to develop a campaign to reduce youth tobacco use. We want to hear your opinions about marketing ideas for this campaign.

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.

The study will take place on [DATE] at your school. It will happen after school hours for 90 minutes. The group leader will ask questions about tobacco use prevention brands and messages. You and the other participants will be asked to share your opinions about the ideas.

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 transcripts 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. Your full name will not be shared with the group leader or other participants. The group leader will ask participants not to share any private, personally identifiable, or inappropriate information. Comments containing this 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. 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 receive a token of appreciation for being in this study?

Everyone who participates in this study will receive a \$25 VISA gift card.

You are eligible for this study. You have been invited to participate in a focus group. However, 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 privacy 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 transcripts 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 call Dana Wagner at Rescue SCG (619-231-7555 x 331) or Jeff Jordan at Rescue SCG (619-231-7555 x 110). If you have any complaints or concerns about this study, please call Institutional Review Board Services at 866-449-8591 (toll-free number) and reference protocol # PBCC1.

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Paperwork Reduction Act Statement: The public reporting burden for this portion of this information collection has been estimated to average 5 minutes per response. You can send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRStaff@fda.hhs.gov.