

---

**PARTICIPANT ASSENT FORM**  
**AGES 12 – 17**

---

**TITLE OF INFORMATION COLLECTION:** Multicultural Campaign: Wave 3 focus group study of reactions to creative advertising concepts designed to prevent multicultural youth tobacco use.

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

**Principal Investigator:** Dana Wagner, PhD

**Email Address of Investigator:** [dana@rescueagency.com](mailto:dana@rescueagency.com)

**Telephone:** 619-231-7555 ext 331 (24 Hours)

**Address:** Rescue Social Change Group  
660 Pennsylvania Ave SE  
Suite 400  
Washington, DC 20003

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) 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 will be one of 180 youth participating in 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 for feedback regarding campaign materials. You and the other participants will be asked to share your opinions. Responses you provided to the screening questions will also be included in the final study.

**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 keep any data that can be used to identify you, such as your full name. **Your contact information will not be shared with others.**

All data, including anything you say in the focus group, will be kept for three years after the study ends. It will be stored on a password-protected computer or in a locked cabinet. Three years after the study ends, 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).**

General information from this study may appear in professional journals or at scientific conferences. We will not disclose any identifiable information about participants in any report or presentation.

#### **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.**

**Will I be paid for being in this study?**

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

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

Your participation in this study is completely voluntary. 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 you leave the focus group early or you choose to not answer some questions.

**Getting answers to your questions or concerns about the study**

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study).

**Contact the investigator or study staff listed on the first page of this form with any questions, concerns or complaints.**

**Getting answers to your questions about your rights as a research subject**

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

For questions about your rights as a research subject, 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](mailto:adviser@chesapeakeirb.com)

Please reference the following number when contacting the Study Subject Adviser:  
Pro00019800.

**PLEASE CHECK ONE OF THE BOXES AND SIGN BELOW.**

**Yes, I agree to participate in this study. I have read, understand, and had time to consider all of the information above. My questions have been answered and I have no further questions.**

**No, I do not agree to participate in this study. I have read, understand, and had time to consider all of the information above. My questions have been answered and I have no further questions.**

\_\_\_\_\_  
*Signature*

\_\_\_\_\_  
*Date*

**Paperwork Reduction Act Statement:** 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 [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).