PARENTAL / GUARDIAN CONSENT FORM

TITLE OF INFORMATION COLLECTION: Focus Group Study of Youth Reactions to Creative Advertising Concepts Designed to Prevent Youth Tobacco Use among Multicultural Youth

Sponsor:	**U.S. Food and Drug Administration's Center for Tobacco Products**
Principal Investigator:	**Dana Wagner, PhD**
Email Address of Investigator:	**dana@rescuescg.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. We will be happy to answer your questions. **Your child is asked to bring the yellow form (signed and dated) with him/her prior to focus group day to take part in the study.**

Introduction: About this study
The purpose of this research is to understand teen culture and gain insights from teens to inform a tobacco prevention brand.

Rescue Social Change Group (Rescue SCG) is a health communications and research company. Rescue SCG has partnered with the U.S. Food and Drug Administration's Center for Tobacco Products (CTP). We are working together to conduct focus groups. Youth ages 12 to 17 will participate in focus groups to provide information that we will use to develop a campaign to reduce youth tobacco use. The study plans to have up to 360 participants.

Procedure: What will my child do during this study?
Your child is invited to take part in an in-person focus group. You and your child can choose to take part in the study or not, regardless of what other parents, guardians or students choose to do. Your child can choose to leave the focus group at any time. You can also withdraw your consent for your child to participate at any time. This will have no effect on your child's standing in the school.

Each group will have no more than 12 participants. The study will take place on _____ at your child's school after school hours for 90 minutes. The group leaders will ask for feedback on campaign materials. Your child and the other participants will be asked to share their opinions. Responses your child provided to screening questions will also be included in the final study.

Privacy: Who will see the information my child provides during this study?
Everything your child says during the focus group can be heard by the other teens, the group

leader, research assistants, and FDA study monitors. All youth will be asked to respect the privacy of the other focus group members. Everyone will be asked to not reveal anything said during the focus group.

Focus group discussions may be audiotaped and transcribed for reporting. Your child can opt out of being audiotaped at the start of the discussion. The report created using the audio transcripts will not link your child's comments to him/her. No one outside of the focus group participants and researchers will know what your child said during the discussions. Your child's name will be used only during the check-in process. The group leader will also instruct youth not to share any private, personal, or inappropriate information during the focus group. Such comments will be removed from the transcripts.

The audio files and transcripts will be stored on a password-protected computer and/or in locked cabinets that only the research team can access. We will collect some personal information including gender, age, and race. However, we will not collect any information that could identify your child, such as his/her full name, address, or social security number.

All information 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 paper documents and permanently deleting electronic information.

All information your child provides will be kept private to the extent allowed 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 about their tobacco-related attitudes, beliefs and behaviors will not be shared with others. This includes parent(s)/guardian(s).**

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

Data from this study may also be used in future research or shared with other researchers. However, anyone who looks at this data will not have your child's name or any other information that could reveal his/her identity.

Incentive: Will my child be paid for being in this study?
Everyone who takes part in this study will receive a $25 VISA or American Express gift card. If your child does not arrive on time to the focus group, he/she may be disqualified.

Study Benefits: What good will come from this study?
This study is not expected to directly benefit you or your child. 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 my child during this study?
We will take care to minimize the potential risks of participating in this study. However, as with all research, there is a chance that privacy could be compromised. For example:

- Everyone will be asked not to discuss any information other participants shared during the study. However, other participants may not keep all information private.

- The research team will do their best to maintain the confidentiality of information collected during the study. A breach may occur from an accident or as a result of hacking.

- Teens will be reminded to not share any private information in the group. However, they may accidentally share such information. This information will be removed from the audio transcripts. Other focus group participants could still hear and react to the information.

Your child may want to discuss tobacco use or prevention with you. Your child may also have questions or concerns about the images or ideas he/she sees during this study. **Your child may stop participating in this study at any time if he/she becomes upset or wants to stop participating.**

Participation and Withdrawal: Does my child have to be in this study? What if my child changes his/her mind?
You and your child can choose to take part in the study or not, regardless of what other parents, guardians or students choose to do. Your child can choose to leave the focus group at any time. You can also withdraw your consent for your child to participate at any time. Contact the principal investigator or the study staff at the telephone number or email address listed on page 1 of this form.

Your child does not have to answer any questions he/she does not want to. Your child will receive the $25 gift card for his/her participation even if he/she chooses to not answer some questions.

Research Questions and Contacts: Whom do I call if my child or I have questions?
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 page 1 of this form. If you have any concerns about this study, please contact Chesapeake IRB.

- 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 welfare of research participants.

In accordance with the Protection of Public Rights Amendment (PPRA), as a parent or guardian are entitled to view any surveys of students taking place in your child's school. To request materials, contact the principal investigator or the study staff at the telephone number or email address listed on page 1 of this form.

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/Guardian Consent Form (the time estimated to read and review). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRAStaff@fda.hhs.gov.