

PARENT / GUARDIAN OPT-OUT FORM

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**TITLE OF INFORMATION COLLECTION:  
Fresh Empire Campaign: Wave 2 Quantitative Study of Reactions to Rough-Cut  
Advertising Designed to Prevent 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@rescuescg.com](mailto: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. **Please contact the researchers if you do not want your child to participate in the study. Contact information is listed above.**

**Introduction: About this study**

The purpose of this research is to determine whether TV ads designed to prevent youth from using tobacco provide an understandable and engaging message about the harms of cigarette smoking.

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 a study with youth ages 12 to 17. The study includes youth in cities across America. The study will show draft versions of TV ads. We then try to learn if the messages are understood. Youth will be randomly assigned to watch either 2 TV ads or none at all. The tested TV ads will be close to final version that still needs small edits. Your child will complete a survey to help make the TV ads final. We want to know which TV ads she/he thinks are understandable and engaging. This study plans to have 855 participants.

**Procedure: What will my child do during this study?**

Your child is invited to complete a survey during an after school study session. The survey itself will take up to 20 minutes to complete. Your child also took a 4-minute screener survey during lunchtime. The study will take place on \_\_\_\_\_ at your child's school. It will happen after school hours.

If your child does not attend the after school session but would still like to participate, we will email him/her a link to the survey to complete it on a personal mobile device or computer with Internet access.

Your child may be asked to view two TV ads and tell us his/her opinions about it. If your child is not shown any TV ads, the survey will take no longer than 5 minutes. Additionally, your child will

be asked questions related to tobacco use and attitudes about tobacco. We may collect information your child provides from both the screener and the study survey.

You and your child can choose to take part in the study or not, regardless of what other parents, guardians, or teens choose to do. Your child can choose to stop taking the survey at any time. You can also withdraw your consent for your child to participate at any time. This will not affect your child's school standing.

**Privacy: Who will see the information my child provides during this study?**

We will take care to protect your child's privacy. The survey will be on a secure website that is password protected. Your child's answers will be kept private to the extent allowable by law. That means we will not share your child's answers with anyone outside the study unless it is necessary to protect him/her, or if required by law. Some personal information, like gender, age, race, and ethnicity, will be gathered. We will also record your child's thoughts, opinions, and reactions to TV ads designed to prevent youth tobacco use. Any personal information that identifies your child will be destroyed at the end of the study. **Information your child shares about their tobacco-related attitudes, beliefs and behaviors will not be shared with others. This includes parent(s)/guardian(s).**

All data will be kept for three years after the completion of the study. It will be stored on a password-protected computer or in a locked cabinet. Three years after completion of the study, we will destroy all of the data by securely shredding paper documents and permanently deleting electronic information.

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.

**Will my child be paid for being in this study?**

Everyone who takes part in the after school study session will receive a \$25 VISA or American Express gift card. Your child will receive this gift card even if he/she decides not to finish the survey during the study session or decides not to answer some questions.

If your child does not attend the after school study session, he/she may be given the opportunity to complete the survey online and receive a \$25 electronic gift card. Your child will receive an email or text message with a link to the survey. He/she will be instructed to click on the link in the email, and complete and submit the survey to receive a gift card. He/she will receive the gift card via email within 72 hours of submitting the survey.

There is no cost to you or your child to participate in this study.

**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 determine whether TV ads about the harms of cigarette smoking are understandable and engaging.

**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.

Your child may want to talk to you about any concerns he/she has about how the ads made him/her feel. Your child may also want to talk with you about any questions or concerns he/she has about using tobacco. If you or your child have any questions about this study, you may call or email the Principal Investigator at the telephone number or email address listed on the first page of this form.

**Participation and Withdrawal: Does my child have to be in this study? What if my child changes his/her mind?**

This study is completely voluntary. You and your child can choose to take part in the study or not, regardless of what other parents, guardians, or teens choose to do. You can also withdraw your consent for your child to participate at any time. There is no penalty or loss of benefits. Contact the principal investigator or the study staff at the telephone number or email address listed on page 1 of this form. Your child will still receive the \$25 gift card even if he/she does not complete the survey during the study session, or he/she chooses not to answer some questions during the study session or the online survey.

The study sponsor or investigator may choose to stop the study at any time.

**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](mailto:adviser@chesapeakeirb.com)

Please reference the following number when contacting the Study Subject Adviser: Pro00009799. An IRB is a group of people who review research studies to protect the rights and safety of research participants.

In accordance with the Protection of Public Rights Amendment (PPRA), as a parent or guardian you 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.

**IMPORTANT:**

**If you do not want your child to participate, you must 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:** The public reporting burden for this information collection has been estimated to average 5 minutes per response to review this 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](mailto:PRStaff@fda.hhs.gov).