OMB# 0910-0674 Exp. 3/31/2016
RETAIN FOR YOUR RECORDS

PARENT / GUARDIAN CONSENT FORM

TITLE OF INFORMATION COLLECTION:
Quantitative Study of Youth Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use among Multicultural Youth

Sponsor:	**The 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 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 this signed and dated form with him/her prior to survey day to take part in the study.**

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 1 or 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 1,410 participants.

Procedure: What will my child do during this study?
Your child is invited to complete a survey after school. The survey itself will take up to 10 minutes to complete. Your child also took a screener survey at lunch. The study will take place on _____ at your child's school. It will happen after school hours.

Your child may be asked to view up to 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 10 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 students 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 digital-based questionnaire 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. 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 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.

Token of Appreciation: Will my child be paid for being in this study?
Everyone who takes part in this study will receive a $20 non-retailer specific gift card. However, if your child does not show up on time to complete the survey, he/she may not be able to participate. Your child will receive this gift card even if he/she decides not to finish the survey or decides not to answer some questions. 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 students 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, Dana Wagner, PhD, at 619-231-7555 ext. 331 or dana@rescuescg.com to withdraw your consent. Your child will still receive the $20 gift card even if he/she does not complete the survey or he/she chooses not to answer some questions.

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 Dana Wagner, PhD, at 619-231-7555 ext. 331 or dana@rescuescg.com. 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: 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, Dana Wagner, PhD, at 619-231-7555 ext. 331 or dana@rescuescg.com..

IMPORTANT:
The informed consent form must be signed by a parent/guardian.

Check one box and sign below:

☐ **I AGREE for my child to take part in this study.**

☐ **I DO NOT AGREE for my child to take part in this study.**

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.

_____

Printed Name of Youth Research Participant

_____	_____	_____
Printed Name of Parent/Guardian	**Signature of Parent/Guardian**	**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 Parent/Guardian Consent Form (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 PRAStaff@fda.hhs.gov.