

PARTICIPANT ASSENT 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

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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 and return it if you want to do the survey.**

Introduction: About this study

The purpose of this research is to determine whether TV ads designed to prevent youth from using tobacco are understandable and engaging

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 multiple cities across America. The study that will show draft versions of TV ads. We then try to learn if the messages are understood. Some participants will view 1 or 2 TV ads. Others will not view an ad. Whether or not you see the TV ads are randomly assigned. If you see the TV ads, they will be close to final version that still needs small edits. You will complete a survey to help make the TV ads final. We want to know which TV ads you think are understandable and engaging.

What will I do during this study?

You are invited to do a survey after school. You will be one of a group of 1,410 youth participating in this study. The survey will take up to 10 minutes to complete. The study will take place on _____ at your school. It will happen after school hours.

You may be asked to view 1 or 2 TV ads and tell us your opinions about them. If you are not shown any ads, the survey will take no longer than 10 minutes. Additionally, you will be asked questions related to tobacco use and your attitudes about tobacco. We may collect information you provide from both the screener and the study survey. You can choose to take part in the study or not, regardless of what other students choose to do. You can choose to stop taking the survey at any time. This will not affect your grades at school in any way.

Who will see the information I provide during this study?

We will take care to protect your privacy. The survey will be on a secure digital-based questionnaire that is password protected. Your answers will be kept private to the extent allowable by law. That means we will not share your answers with anyone outside the study unless it is necessary to protect you, or if required by law. Some personal information, like gender, age, race, and ethnicity, will be gathered. We will also record your thoughts, opinions, and reactions to TV ads designed to prevent youth from using tobacco. Any personal information that identifies you will be destroyed at the end of the study. No one will know what answers you gave us. **Information you share about your tobacco attitudes, beliefs and behaviors will not be shared with others. This includes your parent(s)/guardian(s).**

We will keep answers you provide for three years. The data 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.

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.

Token of Appreciation: Will I be paid for being in this study?

Everyone who participates in this study will receive a \$20 non-retailer specific gift card as a token of appreciation. However, if you do not show up on time to complete the survey, you may not be able to participate. You will receive this gift card even if you decide you do not want to complete the survey. There is no cost to you for taking part in this study.

What good will come from this study?

This study is not expected to directly benefit you. Your answers will help us determine whether TV ads about the harms of tobacco use are understandable and engaging.

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 because of an accidental error or a security breach.

All images will be presented in the context of tobacco use prevention. You should talk to your parents, guardian, or school counselors about any concerns you have about how these images made you feel. You should also talk with them about any questions or concerns you have about using tobacco. If you have any questions about this research study, you may call or email the Principal Investigator at the telephone number or email address listed on the first page of this form.

Remember that you can stop participating in this study at any time.

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

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 stop taking the survey at any time. You do not have to answer any questions you do not want to. You will receive the \$20 gift card even if you do not complete the survey 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 contact the principal investigator or the study staff at the telephone number or email address listed on the first page of this form. If you have any concerns about this study, please 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

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.

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. I agree to take part in this study.

Printed Name of Youth Research Participant

Signature of Youth Research Participant

Date

Printed Name of Witness (Researcher)

Signature of Witness (Researcher)

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 Informed 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 PRAStaff@fda.hhs.gov.