

Form Approved  
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RIHSC #17-093CTP

## PARTICIPANT ASSENT/CONSENT FORM

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### YOUTH ASSENT FOR TEENS AGES 13-17 AND CONSENT FOR ADULTS AGE 18

**TITLE OF INFORMATION COLLECTION:** Multicultural Campaign: Wave 3 Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Multicultural Youth Tobacco Use

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

**Principal Investigator:** Dana Wagner, PhD

**Email Address of Investigator:** [info@whatyouthinksurvey.com](mailto:info@whatyouthinksurvey.com)

**Telephone:** 619-231-7555 ext. 251

**Address:** Rescue Agency  
2437 Morena Blvd.  
San Diego, CA 92110

Please read this form carefully. You can contact the person conducting this study (the Principal Investigator, or PI) at the above email address or phone number. You can ask as many questions as you want. Any question you may have needs to be addressed before you submit this form.

#### **Introduction:**

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

Rescue Agency (Rescue) is a health communications and research company. We are working with the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products to conduct a study with youth ages 13 to 17. The study includes youth across the US. The online study will show draft versions of video ads. We will then try to learn if the messages of the ads are understood. We also want to know if you think the ads are engaging.

#### **What will I do during this study?**

You will be one in a group of 593 people your age participating in this study. Some participants will view one video ad. Others will not view an ad. Whether or not you see the video ad is randomly assigned. If you see the video ad, it will be close to the final version that still needs small edits. You will complete a survey that will help us make the final version of video ad. This survey will take an estimated 25 minutes to complete.

You may be asked to view one video ad and tell us your opinion about it. If you are not shown an ad, the survey will take no longer than 10 minutes to complete. Additionally, you will be asked questions related to tobacco use and your attitudes about tobacco. We may keep information you provide from both the screener and the full study survey.

You can choose to take part in the study or not. You can choose to stop taking the survey at any time.

**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 website that is password protected. 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. The answers you gave earlier, which include gender, age, race, and ethnicity, will be used for study analysis but will not be connected to your personal information such as zip code, email, or IP address. The research team may contact you about the survey using the contact information you provided (your email address, and cell phone number if you shared it). The research team will not use your contact information for any purpose other than contacting you about the survey or delivering your gift card. **Your contact information will not be shared with others.**

De-identified findings from this study, including sample descriptions, may appear in professional journals or at scientific conferences. We will not share your identity in any report or presentation.

We will keep your answers for three years after the end of the study. The data will be stored on a password-protected computer. Three years after the end of the study, we will destroy all of the data by permanently deleting records.

We will not share your answers with anyone outside the study unless it is necessary to protect you, or if required by law (for example, abuse, neglect, self-harm, etc.). **Information you share about your tobacco attitudes, beliefs, and behaviors will not be shared with others. This includes your parent(s)/guardian(s).**

**Study Benefits: 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 for youth.

**Anticipated Risks: Could anything bad happen to me during this study?**

We will take care to protect the data you share. However, as with all studies, there is a chance that privacy could be broken by accident or as the result of hacking. In the unlikely event that the study data are hacked, we will tell you within 5 business days of discovery. We will try our best to maintain the privacy of data collected during the study by using standard online data safeguards.

It is possible that you may not want to answer some questions in the survey. If you do not want to answer a question, you may skip that question. You will still receive your electronic gift card if you choose to skip a question, as long as you submit the survey.

You should talk to your parents, guardian, or school counselors about any concerns you have about how the ad 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.**

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

You will receive a \$10 electronic gift card as a token of appreciation for completing and submitting this survey. You will receive the gift card via email within 72 hours of submitting the survey. There is no cost to you for taking part in this study.

You must submit the survey to receive the gift card. The survey may only be submitted once and you will only receive one \$10 electronic gift card. Fraudulent or duplicate surveys will not be eligible to receive a gift card.

**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 youth 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. If you skip some questions but still submit the survey, you will receive your electronic gift card. If you choose not to submit the survey, you will not receive the electronic gift card.

You will be told about any new information found during the study that may affect whether you want to continue to take part.

**Who do I contact if I have questions now or later?**

If you have any questions about this study, you may contact Dana Wagner or Carolyn Stalgaitis at Rescue (619-231-7555 x 251) or [info@whatyouthinksurvey.com](mailto:info@whatyouthinksurvey.com). This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your child's rights and welfare are protected and that this study is carried out in an ethical manner.

You can ask questions about this consent form or the study (before you decide to start the study or at any time during the study). Questions may include:

- Any payment for being in the study.
- Your rights and your responsibilities as a study subject.
- Other questions.

For questions about your rights as a research subject, contact:

- By mail:  
Study Subject Adviser  
Chesapeake/Advarra 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: Pro00023377.

**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 respond). 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).