

Form Approved  
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RIHSC #17-093CTP

**PARENT / GUARDIAN CONSENT  
Opt-Out Form**

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**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 ask as many questions as you want by contacting the PI of this study at the above email address or phone number. We will be happy to answer your questions. **Please contact the PI if you do not want your child to participate in the study. Contact information is listed above. You can also opt your child out of the study by clicking the link in the email you received and confirming your choice.**

**Introduction:**

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

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

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

Your child will be one of 593 youth participating in this study. Some participants will be asked to view one video ad. Others will not view an ad. Whether or not a teen sees a video ad is randomly assigned. The video ads will be close to the final versions that still need small edits. Your child completing the survey will help make the video ads final. This survey will take up to 25 minutes to complete.

Your child may be asked to view one video ad and tell us his/her opinion about it. If your child is not shown an ad, the survey will take an estimated 10 minutes to complete. Additionally, your child will be asked questions related to tobacco use and attitudes about tobacco. We may keep information your child provides from both the screener and the full study survey.

You and your child can choose to take part in the study or not. 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. To withdraw your consent and exclude your child from the study, you must contact the investigator above or click the link in the email you received and confirm your choice.

**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. 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. The answers your child gave on the Screener, which include gender, age, race, and ethnicity, will be used for study analysis but will not be connected to his/her or your personal information such as email address. The research team may contact your child about the survey using the contact information he/she provided (email address, and cell phone number if he/she shared it). The research team will not use his/her contact information for any purpose other than contacting him/her about the survey or delivering his/her gift card. **You and your child's contact information will not be shared with others.**

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

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

**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 tobacco use are understandable and engaging for youth.

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

We will take care to protect the data your child shares. 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 your child may not want to answer some questions in the survey. If your child does not want to answer a question, he/she may skip that question. Your child will still receive his/her electronic gift card if he/she chooses to skip a question, as long as your child submits the survey.

Your child may want to talk to you about any concerns he/she has about how the ad 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.

**Your child may stop participating in this study at any time if he/she becomes upset or wants to stop participating.**

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

Your child will receive a \$10 electronic gift card as a screened-in token of appreciation for completing and submitting the full survey. He/she will receive the gift card via email within 72 hours of submitting the full survey. There is no cost to you or your child to participate in this study.

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

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

Your child's participation in 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. Your child can choose to stop taking the survey at any time. Your child does not have to answer any survey questions he/she does not want to. If your child skips some questions but still submits the survey, your child will receive his/her electronic gift card. Youth who choose not to submit the survey will not receive the electronic gift card.

You can also withdraw your consent for your child to participate (opt-out) at any time by clicking the link in the email you received or contacting the study investigator listed on the first page of this form. No matter what decision you make, there will be no penalty or loss of benefits to your child.

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

**Getting answers to your questions or concerns about the study**

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 and your child decide to start the study or at any time during the study). Questions may include:

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

For questions about your child's 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.

An IRB is a group of people who review research studies to protect the rights and welfare of research subjects.

**IMPORTANT:**  
**If you do not want your child to participate, you must click the link in the email you received** or contact the principal investigator 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 and review). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).