

RESEARCHER NOTE:

CONSENT PROVIDED

DECLINED CONSENT

UNABLE TO REACH
(CANNOT PARTICIPATE)

PARENT / GUARDIAN CONSENT VERBAL SCRIPT

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

Telephone: 619-231-7555 ext. 331 (24 Hours)

Address: Rescue Social Change Group
660 Pennsylvania Ave SE
Suite 400
Washington, DC 20003

Hello, is this [NAME OF PARENT/GUARDIAN]?

[NO] May I please speak to [NAME OF PARENT/GUARDIAN]?

[IF UNAVAILABLE, ASK FOR BETTER TIME TO CALL] Great, thank you. I will call back then.

[WHEN SPEAKING TO PARENT GUARDIAN, CONTINUE]

Hello, my name is _____ and I'm with Rescue Social Change Group, a health communications and research company. I'm calling because we are conducting research at [INSERT YOUTH FIRST NAME]'s school on [DAY]. Just to confirm, are you [INSERT YOUTH FIRST NAME]'s parent or guardian?

[IF NO] Is [INSERT YOUTH FIRST NAME]'s parent or guardian available, or do you have their contact information? [COLLECT APPROPRIATE INFORMATION AND CALL PARENT/GUARDIAN; IF UNREACHABLE INDEFINITELY, MARK BOX ON 1st PAGE]

[IF YES] We are interested in hearing your child's thoughts and opinions about TV ads that may help prevent youth from using tobacco products. Please be assured that this research does not involve sales of any kind. [INSERT FIRST NAME OF YOUTH] expressed interest in taking part in the study, so we sent home a permission form. Did you happen to read the form?

[IF NO] SKIP TO NEXT PAGE.

[IF YES] Ok, great. Do you have any questions about the study I can answer for you?
[YES] ANSWER QUESTIONS, REFER TO CONSENT ON NEXT PAGE OR
GIVE PHONE TO LEAD RESEARCHER IF UNSURE HOW TO ANSWER.

[NO] READ STATEMENT BELOW AND FILL IN BOX.

Ok. We're trying to finalize our list of which students have their [parents' / guardian's] permission to take part. If you'd like, you can give your answer over the phone. Would you like to give [INSERT NAME OF YOUTH] permission to participate in the research study on [INSERT DAY AND TIME]?

PARENTAL/GUARDIAN CONSENT

AGREES to child taking part in this study.

DOES NOT AGREE to child taking part in this study.

Name of Youth: _____

Name of Parent/Guardian: _____

Relation to Youth: _____

Phone # Confirmation: _____

Date: _____ Time of Call: _____ AM/PM (Circle)

Signature of Researcher (Caller): _____

AFTER FILLING IN BOX, SKIP TO "ENDING CALL" PROCEDURE ON LAST PAGE.

[IF PARENT/GUARDIAN DID NOT READ CONSENT]

Ok, that's not a problem. We gave [INSERT YOUTH FIRST NAME] a permission form for you to sign, but it may have been misplaced. Would you like me to read it to you over the phone, and then you can decide whether to give [HIM/HER] permission to participate?

WAIT FOR CONFIRMATION AND BEGIN. Ok, it will take a few minutes for me to read the entire consent, so please bear with me. Feel free to stop me with any questions or if you need me to repeat anything.

READ ALOUD WORD FOR WORD.

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. We are with Rescue Social Change Group, 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 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.

Your child is invited to complete a survey after school. The survey itself will take up to 20 minutes to complete, plus the 4-minute screener survey your child took at lunch. The study will take place on [DATE] at your child's school. It will happen after school hours.

If your child is age 13 or older and 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 his/her 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.

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 from using tobacco. 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 information will be kept for three years after 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.

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 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.

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.

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 has any questions about this research study, you may call or email the Principal Investigator at [INSERT PI TELEPHONE NUMBER] or [INSERT PI EMAIL ADDRESS].

This study is completely voluntary. You and your child can choose to take part in the study or not, regardless of what other parents 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. Would you like to write down the study investigator's name and contact information? [If YES: that's [INSERT PI NAME] at Rescue SCG [INSERT PI TELEPHONE NUMBER AND EMAIL ADDRESS]]

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.

I can also give you contact information for the research ethics board that oversees this study. Would you like that? [If YES]: Contact the Study Subject Adviser at Chesapeake IRB,

- 877-992-4724
- adviser@irbinfo.com

Please reference the following number Pro00009799.

In accordance with the Protection of Public Rights Amendment (PPRA), as a [parent/guardian] you are entitled to view any surveys of students taking place in your child's school. To request materials, contact Dana Wagner at the number I gave you.

Would you like to give [INSERT NAME OF YOUTH] permission to participate in the research study on [INSERT DAY AND TIME]?

PARENTAL/GUARDIAN CONSENT

- AGREES to child taking part in this study.**
 DOES NOT AGREE to child taking part in this study.

Name of Youth: _____

Name of Parent/Guardian: _____

Relation to Youth: _____

Phone # Confirmation: _____

Date: _____ Time of Call: _____ AM/PM (Circle)

Signature of Researcher (Caller): _____

ENDING CALL

[IF CONSENT NOT PROVIDED] Ok, well, thanks anyway for taking the time to talk to me. Have a good morning/afternoon/evening.

[IF CONSENT PROVIDED] Great, thank you. I can send you a copy of the consent form so you'll have it for your records. Would you like me to mail, email, or fax it to you?

[IF YES] GET ADDRESS OR FAX #.

[IF NO] OFFER TO REPEAT ANY PART VERBALLY.

Please understand that what your [CHILD/SON/DAUGHTER/GRANDSON/GRANDDAUGHTER, ETC] says is important to us.

It is very important that [HE/SHE] arrive right on time to complete the survey. Please remind [HIM/HER] about the survey on [DAY] at [TIME]. Before we end the call, do you have any questions for me?

ANSWER QUESTIONS OR WAIT FOR "NO"

Ok, great. Thank you so much for your time. Have a good morning/afternoon/evening.

UPDATE RESEARCHER NOTE ON FIRST PAGE.