

RESEARCHER NOTE:

- CONSENT PROVIDED**
- DECLINED CONSENT**
- UNABLE TO REACH
(CANNOT PARTICIPATE)**

PARENTAL / GUARDIAN CONSENT VERBAL SCRIPT

TITLE OF INFORMATION COLLECTION: Multicultural Campaign: Wave 3 focus group study of reactions to creative advertising concepts designed to prevent multicultural 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@rescueagency.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, 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 teen culture and other information 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 [parent's/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)

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above-named parent/guardian.

Name of Researcher (Caller): _____

Signature of Researcher (Caller): _____

Name of Witness: _____

Signature of Witness: _____

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

[IF PARENT 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 understand teen culture and gain insights from teens to inform a tobacco prevention brand. We are with Rescue Social Change Group, a health

communications and research company. Rescue has partnered with the U.S. Food and Drug Administration's Center for Tobacco Products. We are working together to conduct focus groups. Youth ages 12 to 17 will participate in focus groups to provide information that we will use to develop a campaign to reduce youth tobacco use.

[PROCEDURE]

Your child will be one of 180 youth participating in this study. Your child is invited to take part in an in-person focus group. You and your child can choose to take part in the study or not, regardless of what other parents or students choose to do. Your child can choose to leave the focus group at any time. You can also withdraw your consent for your child to participate at any time. This will have no effect on your child's standing in the school.

Each group will have no more than 12 participants. The study will take place on [DATE] at your child's school after school hours for 90 minutes. The group leader will ask for feedback on tobacco prevention campaign materials. Your child and the other participants will be asked to share their opinions. Responses your child provided to screening questions will also be included in the final study.

[PRIVACY]

Everything your child says during the focus group can be heard by the other teens, the group leader, research assistants, and FDA study monitors. All youth will be asked to respect the privacy of the other focus group members. Everyone will be asked to not reveal anything said during the focus group.

Focus group discussions may be audiotaped and transcribed for reporting. Your child can opt out of being audiotaped at the start of the discussion. The report created using the audio transcripts will not link your child's comments to [him/her]. No one outside of the focus group participants and researchers will know what your child said during the discussions. Your child's name will be used only during the check-in process. The group leader will also instruct youth not to share any private, personal, or inappropriate information during the focus group. Such comments will be removed from the transcripts.

The audio files and transcripts will be stored on a password-protected computer and/or in locked cabinets that only the research team can access. We will collect some personal information including gender, age, and race. However, we will not keep any information that could identify your child, such as his/her full name. **Your and your child's contact information will not be shared with others.**

All information will be kept for three years after the study ends. It will be stored on a password-protected computer or in a locked cabinet. Three years after the study ends, we will destroy all of the data by securely shredding paper documents and permanently deleting electronic information.

All information your child provides will be kept private to the extent allowed by law. This means that we will not share information with anyone outside of the study unless it is necessary to protect your child, or if it is required by law. Information your child shares about their tobacco-related attitudes, beliefs and behaviors will not be shared with others, including you.

De-identified data from this study, including sample descriptions, may appear in professional journals or at scientific conferences. We will not disclose your child's identity in any report or presentation. The Department of Health and Human Services and Chesapeake IRB may have

access to the study data.

[BENEFITS]

This study is not expected to directly benefit you or your child. Your child's feedback will help us decide what ideas, images, and messages may prevent youth tobacco use.

[ANTICIPATED RISKS]

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. For example:

- Everyone will be asked not to discuss any information other participants shared during the study. However, other participants may not keep all information private.
- The research team will do their best to maintain the confidentiality of information collected during the study. A breach may occur from an accident or as a result of hacking.
- Teens will be reminded to not share any private information in the group. However, they may accidentally share such information. This information will be removed from the audio transcripts. Other focus group participants could still hear and react to the information.

Your child may want to discuss tobacco use or prevention with you. Your child may also have questions or concerns about the images or ideas he/she sees during this study. Your child may stop participating in this study at any time if he/she becomes upset or wants to stop participating.

[REIMBURSEMENT]

Every child who takes part in this study will receive a \$25 VISA or American Express gift card. If your child does not arrive on time to the focus group, [he/she] may be disqualified. There is no cost for taking part in this study.

[PARTICIPATION AND WITHDRAWAL]

Your child does not have to take part in this study. 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 or students choose to do. Your child can choose to leave the focus group at any time. You can also withdraw your consent for your child to participate at any time. No matter what decision you make, there will be no penalty or loss of benefits to your child. Would you like to write down the study investigator's name and contact information? [If YES: that's Dana Wagner at Rescue (619-231-7555 x 331; dana@rescueagency.com)]

Your child does not have to answer any questions [he/she] does not want to. Your child will receive the \$25 gift card for his/her participation even if [he/she] chooses to leave the focus group early or chooses to not answer some questions.

If you have any concerns about this study, please ***contact the investigator or study staff listed on the first page of this form with any questions, concerns or complaints.***

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.

For questions about your child's rights as a research subject, 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:
Pro00019800.

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)

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above-named parent/guardian.

Name of Researcher (Caller): _____

Signature of Researcher (Caller): _____

Name of Witness: _____

Signature of Witness: _____

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.