

RESEARCHER NOTE:

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

OMB# 0910-0674 Exp: 3/31/2016

**Informed Consent for Multicultural Youth Tobacco Prevention Campaign:
Pilot (Brand and Creative Concept Phase)
PARENTAL CONSENT VERBAL SCRIPT UNDER 13**

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 SCG, a research and marketing 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 marketing materials 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' 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 CONSENT

AGREES to child taking part in this study.

DOES NOT AGREE to child taking part in this study.

Name of Person: _____

Relation to Youth: _____

Phone # Confirmation: _____

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

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 teens' opinions about tobacco prevention marketing materials. Rescue Social Change Group Rescue SCG is a social marketing company partnering with the U.S. Food and Drug Administration's Center for Tobacco Products. Rescue SCG will conduct focus groups with youth in Atlanta, GA and Charlotte, NC. Youth aged 12 to 17 will participate in focus group activities to provide information that we will use to develop a campaign to reduce youth tobacco use. We will collect their thoughts and opinions about marketing materials that may help prevent other youth from using tobacco.

[PROCEDURE]

Your child is invited to take part in one of 10 in-person focus groups. 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.

Each group will have no more than 12 participants. The focus group will occur in your child's school. The study will take place on **[DATE]** at your child's school after school hours for 90 minutes. The group leader will ask questions about tobacco use prevention brands and messages. Your child and the other participants will be asked to share their thoughts and opinions about these items.

[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 purposes. Your child can opt out of being audiotaped at the start of the discussion. The report generated using the audio transcripts will not link your child's comments to him/her. The report also will not include his/her full name. 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. His/her full name will not be shared with the group leader or other participants. The group leader will also instruct youth not to share any private, personally identifiable, or inappropriate information during the focus group. Comments containing private or personally identifiable information 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 collect any information that could identify your child, such as his/her full name, address, or social security number.

All information, including anything your child said in the focus group, will be kept for three years. It 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 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. This includes parent(s)/guardian(s).

Data from this study may appear in professional journals or at scientific conferences. No individual participant will be identified or linked to the results. 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. Anyone who looks at this data will not have your child's name or any other information that could reveal his/her identity.

[TOKEN OF APPRECIATION]

Everyone who takes part in this study will receive a \$25 gift card as a token of appreciation for their participation in this study. Your child is eligible to participate. He/she has been invited to join the discussion groups. However, if your child does not arrive on time to focus group location, he/she may be disqualified.

[BENEFITS]

This study is not expected to directly benefit you or your child. However, 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 confidentiality 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.
- Despite the best efforts of the research team to maintain the confidentiality of information collected during the study, a privacy breach may occur from accidental human error or by as a result of hacking.
- Although youth will be reminded to not share any private, personally identifiable, or inappropriate information, they may accidentally share such information. This information will be removed from the audio transcripts. However, it is important to understand that 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 concepts 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.**

[PARTICIPATION AND WITHDRAWAL]

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 by contacting Dana Wagner at Rescue SCG (619-231-7555 x 331) or Jeff Jordan at Rescue SCG (619-231-7555 x 110).

Your child does not have to answer any questions he/she does not want to. Your child will receive the \$25 incentive for his/her participation even if he/she chooses to not answer some questions.

If you have any questions about this study, or about your child's rights as a participant in this study, please call Dana Wagner at Rescue SCG (619-231-7555 x 331) or Jeff Jordan at Rescue SCG (619-231-7555 x 110). If you have any complaints or concerns about this study, please call Institutional Review Board Services at 866-449-8591 (toll-free number) and reference protocol # PBCC1. **[REPEAT IF NECESSARY]**

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

PARENTAL CONSENT	
<input type="checkbox"/>	AGREES to child taking part in this study.
<input type="checkbox"/>	DOES NOT AGREE to child taking part in this study.
Name of Person: _____	
Relation to Youth: _____	
Phone # Confirmation: _____	
Date: _____ Time of Call: _____ AM/PM (Circle)	

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.

[IF NO] OFFER TO REPEAT ANY PART VERBALLY.

Please understand that what your **[SON/DAUGHTER/GRANDSON/GRANDDAUGHTER,ETC]** says is important to us. It is very important that **[HE/SHE]** arrive right on time so that the group may begin on time. Please remind **[HIM/HER]** about the focus group 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.

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Paperwork Reduction Act Statement: The public reporting burden for this portion of this information collection has been estimated to average 5 minutes per response. You can send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRStaff@fda.hhs.gov.