RESEARCHER NOTE:
- ☐ **CONSENT PROVIDED**
- ☐ **DECLINED CONSENT**
- ☐ **UNABLE TO REACH (CANNOT PARTICIPATE)**

OMB# 0910-0796
Exp. 07/31/2021

PARENT / GUARDIAN PERMISSION VERBAL SCRIPT

TITLE OF INFORMATION COLLECTION: Developing Brand and Creative Concepts Designed to Prevent AI/AN Youth Tobacco Use

Sponsor: **U.S. Food and Drug Administration**
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 Agency**
2437 Morena Blvd
San Diego, CA 92110

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

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

[IF UNAVAILABLE, ASK FOR A 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 holding discussion groups in your area. 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 messaging 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 discussion group, so we sent home a permission form. Did you happen to read the form?

[IF NO, SKIP TO NEXT PAGE AND FOLLOW INSTRUCTIONS STARTING AT "IF PARENT DID NOT READ PERMISSION FORM"].

[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 youth who 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 discussion groups on [INSERT DAY AND TIME]?

PARENTAL/GUARDIAN PERMISSION

☐ **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 PERMISSION FORM]

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?

[IF NO, SKIP TO THE "ENDING CALL" SECTION ON THE LAST PAGE AND FOLLOW INSTRUCTIONS FOR "IF PERMISSION NOT PROVIDED."]

[IF YES]. Ok, it will take a few minutes for me to read the entire permission form, 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.

[KEY INFORMATION]
The purpose of this research study is to gain insights from youth ages 13 to 17 on teen culture and their reactions to campaign brands and creative concepts to inform a tobacco prevention educational campaign. During a 90-minute discussion group, youth will complete surveys individually and participle in group discussions. The U.S. Food and Drug Administration's (FDA) Center for Tobacco Products is sponsoring this study.

If your child is invited to participate, your child's participation in this discussion group is completely voluntary. You and your child can choose to take part in the discussion group or not, regardless of what others choose to do. No information your child shares will be shared with others outside the discussion group, and nothing said by participants during the discussion group will be attributed to any participant. Your child can choose to leave the discussion group at any time. Your child does not have to answer any questions he/she does not want to. This discussion group 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. Every youth who participates in this discussion group will get $25. You or another adult who brings your child to the group will also get $25.

[INTRODUCTION]
Rescue Agency (Rescue) is a health communications and research company who is working with G+G Advertising (G+G), an American Indian communications company. Together we are working with the U.S. Food and Drug Administration's Center for Tobacco Products to hold discussion groups with youth ages 13 to 17. Information we get from youth participants will be used to develop a campaign to reduce youth tobacco use.

[PROCEDURE]
Your child will be one of up to 192 youth participating in this project. Your child is invited to take part in an in-person discussion group with no more than 16 youth. You can choose to let your child take part in the discussion group or not, regardless of what others choose to do. Your child can choose to leave the group at any time.

If your son or daughter is invited to take part, a Rescue staff member will contact them or you with the date and time of the discussion group. The group will last 90 minutes. Discussion group leaders will ask for feedback about teen culture and future 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 reports. However, your child's name will never be used.

[PRIVACY]
Everything your child says during the discussion group can be heard by the other youth in the group, the group leader, and other research team members. All participants will be asked to respect the privacy of the others in the group. Everyone will be asked to not share anything said during the group.

Group discussions may be audiotaped and transcribed. Your child can choose not to be audiotaped at the start of the session. If your child says no, we will not record the group. We will take written notes instead. Groups may also be live-streamed so that project staff who cannot travel can watch the groups. Groups will not be video recorded. The report will not link your child's comments to him/her. No one (including parents or guardians) outside of the group participants and researchers will know what your child said during the discussions. Your child's name will be used during check-in and during the discussion, but comments will not be traced back to your child.

Any audio files, transcripts or written notes resulting from a discussion group 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. You or your child will not be re-contacted about this discussion group. The sponsor and Advarra Institutional Review Board (IRB) may have access to the study data.

All data will be kept for three years after the project ends. It will be stored on a password-protected computer or in a locked cabinet. Three years after the discussion group ends, we will destroy all of the data by securely shredding paper documents and permanently deleting electronic records. All identifiable information (for example, contact information such as name and phone number) will be destroyed after data collection for the project. The FDA will not receive any data that could identify your child.

This research is covered by a special protection (called a Certificate of Confidentiality) from the FDA. This special protection requires that staff involved in this project protect your child's privacy. This means project staff generally cannot provide your child's name, or any other information that could identify your child, to anyone who is not connected with the project. Project staff cannot share this information in court or during other legal proceedings, unless you or your child agree, even if there is a court order for the information. However, in other settings, project staff may share study information that could identify your child if:

- you or your child agree to share information (for example, to get medical treatment);
- the study information is used for other scientific research that follows federal law;
- the FDA, which is paying for the project, needs information to check how their research money is being spent; or
- a law requires sharing information (for example, when project staff must report to FDA, or if project staff hear threats of harm to others or reports of child abuse).

The Certificate of Confidentiality does not prevent you and your child, however, from sharing any personal information or information about your child's involvement in this study with others. For example, you can share that your child is taking part in this project or your child's history of tobacco use.

Information your child shares about their tobacco-related attitudes, beliefs and behaviors will not be shared with others. This includes parent(s)/guardian(s).

General information from this discussion group, including sample descriptions, may appear in professional journals or at scientific conferences, but will never include any identifying information about your child.

[BENEFITS]
This discussion group 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 discussion group. 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 discussion group. However, other participants may not keep all information private.
- The research team will do their best to keep the confidentiality of information collected during the discussion group. A breach may occur from an accident or as a result of hacking.
- Teens will be reminded not to share any private information in the group. However, they may accidentally share such information. This information will not be included in any written notes and will be removed from the audio transcripts. Other discussion 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 discussion group.

[FINANCIAL COMPENSATION]
Every youth who participates in this discussion group will get $25. You or another adult who brings your child to the group will also get $25. If your child does not arrive on time to the discussion group location, he/she may be disqualified. There is no cost for taking part in this discussion group.

[INFORMATION USE]
Information will solely be used for research purposes. As will be mentioned in the following Confidentiality section, your child's information will only be shared at an aggregate level and will not have any personally identifiable information. Even if the identifiers are removed, the information from this research study will never be used or distributed in a future research study.

[PARTICIPATION AND WITHDRAWAL]
Your child does not have to take part in this discussion group. Your child's participation in this discussion group is completely voluntary. You and your child can choose to take part in the discussion group or not, regardless of what others choose to do. **Your child may stop participating in this discussion group at any time if he/she wants to stop participating.** You can also withdraw your permission for your child to participate at any time by contacting the principal investigator at the top of this document. No matter what decision you make, there will be no penalty or loss of benefits to your child.

Your child does not have to answer any questions he/she does not want to. Your child will receive $25 for his/her participation even if he/she chooses to leave the discussion group early or chooses not to answer some questions. You or the adult who brings your child will still get $25 for bringing them. If your child is disruptive during the focus group, the group leader may ask them to leave the discussion. They would still receive $25.

During the study, if you or your child have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your child's rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail: Participant Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Participant Adviser: Pro00033326.

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

PARENTAL/GUARDIAN PERMISSION

☐ **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: _____

ENDING CALL

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

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

[IF YES] GET ADDRESS OR EMAIL.

[IF NO] OFFER TO REPEAT ANY PART VERBALLY.

Please understand that what your [CHILD/SON/DAUGHTER/GRANDSON/ GRANDDAUGHTER, ETC] says is important to us. The discussion group will last 90 minutes, from [START TIME TO END TIME]. All youth will need to check-in prior to participating in the discussion group. Check-in will begin 30 minutes prior to the discussion group, at [TIME]. It is very important that [HE/SHE] arrive for check-in so that the discussion group may begin on time. Please remind [HIM/HER] about the discussion 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.

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete the Parent/Guardian Verbal Consent Form (the time estimated to respond and complete). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRAStaff@fda.hhs.gov