

PARENT / GUARDIAN PERMISSION FORM

TITLE OF INFORMATION COLLECTION: Developing strategic 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

Please read this form carefully. You can ask as many questions as you want. We will be happy to answer your questions.

Introduction:

The purpose of the research study your child has been invited to take part in is to learn about teen culture and get opinions from teens to inform a tobacco prevention educational campaign.

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 12 to 17. Information we get from youth participants will be used to develop a campaign to reduce youth tobacco use.

Procedure: What will my child do during this discussion group?

Your child will be one of 168 youth participating in this project. Your child is invited to take part in an in-person discussion group with no more than 12 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 researcher will contact them or you with the date and time of the discussion group. The group will last 90 minutes. The group leaders will ask for feedback about teen culture and existing advertisements. 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: Who will see the information my child provides during this discussion group?

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. 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 only during check-in.

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 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.

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 discussion group unless it is necessary to protect your child, or if it is required by law (for example, abuse, neglect, self-harm, etc.). **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.

Discussion Group Benefits: What good will come from this discussion group?

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: Could anything bad happen to my child during this discussion group?

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 to not 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.

Will my child get anything for being in this discussion group?

Every youth who participates in this discussion group will get \$25. You or another adult who drives your child and any other teens to the group will also get \$25. That amount will only be given to an adult driving one or more children to the discussion group, it is not given to a child who arrives by himself or herself, and the same amount is provided no matter how many children are transported. 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.

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

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 to not answer some questions. You or the adult who drives your child will still get \$25 for driving them.

Getting answers to your questions or concerns about the discussion group

You and your child can ask questions about this permission form or the discussion group (before you decide to let your child start the discussion group, at any time during the group, or after completion of the group).

The FDA does not encourage the use or sale of tobacco products. It is illegal in most states for people younger than 18 years old to use tobacco, and it is illegal in all states for people under 18 to buy tobacco. Contact the staff listed on the first page of this form with any questions, concerns or complaints.

Getting answers to your questions about your rights as a research participant

This project has been reviewed by an Institutional Review Board (IRB). The IRB reviewed this research study to help ensure that your child's rights and welfare are protected and that this discussion group is carried out in an ethical manner.

For questions about your child's rights as a research participant, 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: Pro00024887.

Parent Opt-Out for 14-17 Year Olds

If your son or daughter is 14-17 years old, your signature on this form **is not required** for their participation in the discussion group.

If you do not want your 14-17 year old child to participate, you must either 1) Contact the Principal Investigator or study staff to let them know you do not want your child to take part (Dana Wagner, dana@rescueagency.com, 619-231-7555 ext 331) or 2) Check the box below indicating below you DO NOT agree for your son/daughter to participate and return this form.

Parent Permission for 12-13 Year Olds

If your son or daughter is 12-13 years old, your signature on this form (or verbal consent by phone) **is required** for their participation in the discussion groups. All 12-13 year olds **MUST** return this form signed in order to participate in a discussion group. If not, a member of the research staff may contact you to get your verbal consent by phone.

PLEASE CHECK ONE OF THE BOXES AND SIGN BELOW.

Yes, I agree for my son or daughter to participate in this discussion group. I have read, understand, and had time to consider all of the information above. My questions have been answered and I have no further questions.

No, I do not agree for my son or daughter to participate in this discussion group. have read, understand, and had time to consider all of the information above. My questions have been answered and I have no further questions.

Child's Name (Print)

Parent/Guardian Signature

Date

Parent/Guardian Printed Name

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete the Parental Permission Form (the time estimated to read, review, and complete). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRASStaff@fda.hhs.gov.