

PARTICIPANT ASSENT FORM
Youth 12 - 17

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

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Please read this form carefully. You can ask as many questions as you want. If there is anything you do not understand, researchers can explain it to you. Any question you may have needs to be addressed before you sign this form.

Introduction:

The purpose of this research study 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. We will use this information to develop a campaign to reduce youth tobacco use.

What will I do during this discussion group?

You will be one of 168 youth participating in this project. You are invited to take part in an in-person discussion group with no more than 12 youth. You can choose to take part in the discussion group or not, regardless of what other youth choose to do. You can choose to leave the group at any time.

The discussion group will take place on _____ at _____ and it will last 90 minutes. The group leaders will ask for feedback about teen culture and existing ads. You and the other participants will be asked to share your opinions. Responses you provided to the screening questions will also be included in reports. However, your name will never be used.

Who will see the information I provide during this discussion group?

Everything you say during the discussion group can be heard by the others 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. You can choose not to be audiotaped at the start of the session. If you say no, we will not record the group. We will take written notes instead. The written notes will not be used to link your comments to you. No one, (including parents or guardians) beyond the other participants and the researchers will know what you said during the discussions. Your name will be used only during check-in. The group leaders will ask participants not to share any private, personal, or inappropriate information. Comments containing this information will be removed from the notes.

The audio files and notes will be stored on a password-protected computer and/or in locked cabinets. Only research team members will have access to these items. We will collect some personal information such as gender, age, and race. We will not keep any data that can be used to identify you, such as your full name. **Your contact information will not be shared with others.**

All data, including anything you say in the discussion group, 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 and permanently deleting records.

We will not share information with anyone outside of the discussion group unless it is necessary to protect you, or if it is required by law (for example, abuse, neglect, self-harm, etc.).

Information you share about your tobacco attitudes, beliefs and behaviors will not be shared with others. This includes your parent(s)/guardian(s).

General information from this discussion group may appear in professional journals or at scientific conferences. We will not use any identifiable information about participants in any report or presentation.

What good will come from this discussion group?

This discussion group is not expected to directly benefit you. However, your opinions will help us decide what ideas may prevent youth tobacco use.

Could anything bad happen to me during this discussion group?

We will take care to protect the data you provide. However, as with all studies, there is a chance that privacy could be broken. For example:

- Everyone will be asked not to discuss anything other participants share during the discussion group. However, other participants may not keep all information private.
- We will try our best to keep the privacy of data collected during the discussion group. Still, a breach could occur by accident or as a result of hacking.
- Participants will be reminded to not share anything private or inappropriate information. However, they may accidentally share such information. This data will be removed from the notes but other participants could still hear it.

If you have any questions about tobacco use or prevention, you can ask the group leader. You can also talk to your parent(s)/guardian(s), a teacher, or a school counselor.

Remember that you can leave the discussion group at any time.

Will I get anything for being in this discussion group?

Everyone who participates in this discussion group will get \$25 cash. You have been invited to participate in a discussion group. However, if you do not arrive on time to the discussion group, you may be disqualified. An adult, such as your parent or guardian, who drives you and any other teens to the group will also get \$25 cash. The \$25 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 to the driver no matter how many children are transported.

Do I have to be in this discussion group? What if I want to drop out?

Your participation in this discussion group is completely up to you. You can choose to take part in the discussion group or not, regardless of what others choose to do. You can choose to leave the discussion group at any time. You do not have to answer any questions you do not want to. You will get \$25 even if you leave the discussion group early or you choose to not answer some questions.

Getting answers to your questions or concerns about the discussion group

You can ask questions about this form or the discussion group (before you decide to start the group, at any time during the group, or after the end of the group).

Contact the investigator or discussion group 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). This Committee reviewed this discussion group to help ensure that your rights and welfare are protected and that this discussion group is carried out in an ethical manner.

For questions about your 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.

PLEASE CHECK ONE OF THE BOXES.

Yes, I agree to be audio-recorded as part of this discussion group.

No, I do not agree to be audio-recorded as part of this discussion group.

PLEASE CHECK ONE OF THE BOXES AND SIGN BELOW.

Yes, I agree 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 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.

Signature

Date

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete the Youth Assent 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.