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

PARTICIPANT ASSENT FORM

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**

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 Center for Tobacco Products is sponsoring this study.

If you are invited to participate, it is your choice whether you participate or not, regardless of what others choose to do. No information you share will be shared with others outside the discussion group, and nothing said by participants during the discussion group will be attributed to any participant. You can choose to leave the discussion group at any time. You do not have to answer any questions you do not want to. This discussion group is not expected to directly benefit you. Your feedback will help us decide what ideas, images, and messages may prevent youth tobacco use. You will receive $25 for participating, even if you leave the discussion group early or choose not to answer some questions. The parent/guardian who brings you will also receive $25.

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

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. 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 up to 192 youth participating in this project. You are invited to take part in an in-person discussion group with no more than 16 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 and still receive $25.

The discussion group will take place on _____ at _____ and it will last 90 minutes. Discussion group leaders will ask for feedback about teen culture and future campaign materials. 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 or contact information 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 not to 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. Groups may also be live-streamed so that project staff who cannot travel can watch the groups. Groups will not be video recorded. The written notes will not be used to link your comments to you. Your name will be used during check-in and during the discussion, but comments will not be traced back to you personally. 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.

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.

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 privacy. This means project staff generally cannot provide your name, or any other information that could identify you, to anyone who is not connected with the project. Project staff cannot share this information in court or during other legal proceedings, unless you agree, even if there is a court order for the information. However, in other settings, project staff may share study information that could identify you if:

- you 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 study, 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 from sharing any personal information or

information about your involvement in this study with others. For example, you can share that you are taking part in this project or your history of vaping or tobacco use.

No one, including parents or guardians, beyond the other participants and researchers will know what you said in 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, including 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, like your name, 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 not to share anything private or provide 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 is invited and participates in this discussion group will get $25. However, if you do not arrive on time to the discussion group, you may be disqualified.

How will my information be used?
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.

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 not to answer some questions. You could be asked by the group leader to leave the discussion if you are acting badly, however, you would still receive $25.

Whom to contact about this study
During the study, if you 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 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.

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 AND DATE 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.**

_____ _____

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 Participant 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 PRAStaff@fda.hhs.gov.