

PARTICIPANT CONSENT FORM

TITLE OF INFORMATION COLLECTION: Nicotine Education Project: Qualitative Study to Gain Insights from Adult Current and Former Smokers to Educate the General Public about Changing Nicotine Standards

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Center for Tobacco Products

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Key Information:

The purpose of this research study is to gain insights from current and former adult smokers, ages 19 to 54, on nicotine, addiction, smoking behaviors, tobacco use, and awareness of nicotine related regulatory actions to inform strategies for a potential health communication effort. During a 90-minute discussion group, you will complete surveys individually and participate in group discussions. The U.S. Food and Drug Administration's Center for Tobacco Products is sponsoring this study.

Your participation in this discussion group is completely voluntary. You can choose to take part in the discussion group 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 and messages could be used to educate the public about nicotine in general and how a potential nicotine related regulatory action might affect smokers. Every person who participates in this discussion group will receive \$75 as a token of appreciation for your time.

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

Introduction:

Rescue Agency (Rescue) is a health communications and research company who is working with FCB New York (FCB), an advertising agency. Together we are working with the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products to hold discussion groups with adults ages 19 to 54. Information we get from participants will be used to inform strategies for a potential health communication effort to educate the public about the role of nicotine in tobacco and addiction.

What will I do during this discussion group?

You will be one of up to 240 people participating in this project. You are invited to take part in an in-person discussion group with no more than 8 total participants. 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 group at any time.

The discussion group will take place on _____ at _____ and it will be 90 minutes. Discussion group leaders will ask for feedback about knowledge and perceptions around tobacco products, smoking habits, and nicotine related regulatory actions. You will be asked to share your opinions. However, your name will never be used in any reports.

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

Everything you say during the discussion group can be heard by the other adults 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. Groups may also be live-streamed so that project staff who cannot travel can watch the groups. Groups will not be video recorded. The transcripts 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. The group leaders will ask participants not to share any private, personal, or inappropriate information. Comments containing this information will be removed from the transcripts. The report will not link your comments to you. No one outside of the group participants and researchers will know what you said during the discussions.

The audio files and transcripts 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), as required by Health and Human Services. 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 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, however, 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 tobacco use.

No one 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 about your tobacco-related attitudes, beliefs and behaviors will not be shared with others.**

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 you.

What good will come from this discussion group?

This discussion group is not expected to directly benefit you. Your feedback will help us gain early insights on promising messaging areas for a potential health communication effort.

Could anything bad happen to me 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.
- Participants 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.

Additionally, during the discussion group we will talk about nicotine and tobacco use. These topics may be uncomfortable for you or trigger tobacco cravings. We will ensure that participants in any sort of distress as a result of the discussion group receive information and resources on quitting and staying quit.

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

Will I get anything for being in this discussion group?

Every person who participates in this discussion group will get \$75 as a token of appreciation. If you do not arrive on time to the discussion group location, you may be disqualified. There is no cost for taking part in this discussion group.

Do I have to be in this discussion group? What if I change my mind?

Your participation in this discussion groups 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 \$75 even if

you leave the discussion group early or you choose not to answer some questions. If anyone is disruptive during the focus group, the group leader may ask them to leave the discussion. They would still receive \$75.

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.

This project has been reviewed by an Institutional Review Board (IRB). The IRB reviewed this research study 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:** cirbi@advarra.com

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

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.**

Participant's Name (Print)

Participant's 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 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 PRStaff@fda.hhs.gov.

