FOCUS GROUP CONSENT FORM

Sponsor / Study	CDC / Menthol-Flavored Tobacco Product Restriction
Title:	Policy Evaluation

Principal Investigator:	Dr. Cathy Lesesne, Ph.D.
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Informed Consent Statement:

We are asking 75 adults aged 18 and older to participate in web-based focus groups for an evaluation of policies restricting access to menthol tobacco products. These focus groups will focus on participant knowledge, perceptions, and behaviors related to menthol and non-menthol tobacco products. You are being recruited for this focus group because you live in one of the communities selected for this study. Based on your responses to the focus group screening questionnaire, you may be placed in a LGBTQ+ or racial and ethnic minority-specific focus group. This research is being funded by and conducted on behalf of the Centers for Disease Control and Prevention (CDC).

Opting into this focus group confirms that you are participating of your own free will. You are also allowing project staff to store and share information collected from the focus group. Please note, this focus group will consist of six to eight participants and will be audio and video recorded for transcription purposes only. The recording will be deleted once analysis of the transcription is complete. Nothing you share will be tied back to you. Transcription data will be transferred to CDC's encrypted, password-protected network for storage for a minimum of three years.

Participating in this focus group will cause little or no risk to you, but there may be risks that we cannot predict. There is always a risk that other participants in the focus group will break confidentiality agreements. To reduce this risk, we will ask you to only provide your first name during the focus group discussion (including on the screen). There may be a risk of discomfort since some of the questions are personal in nature. To reduce this risk, participation is voluntary, and you do not have to answer any questions or participate in any discussions that cause you discomfort. Choosing to skip questions will not result in penalty or loss of compensation.

The focus group should take about 60 minutes. You will not benefit from taking part in this study outside of compensation for your time in the form of a \$45 Visa gift card, but the study may help others in the future by supporting public health programs and services. Gift cards will be emailed upon completion of the focus group.

If you consent, you will be contacted to determine your availability for the focus group.

If you have any questions, concerns, or complaints about the study, please contact Dr. Cathy Lesesne at 404-270-0513 or at <u>clesesne@deloitte.com</u>. If you have questions about the study's funding, please reach out to Katie Moran at 516-743-7727 or at <u>rtq@cdc.gov</u>. If you have questions about your rights as a research subject, you may contact Solutions IRB at (855) 226-4472 or <u>participants@solutionsirb.com</u>. Solutions IRB and other regulatory bodies may review the research materials (e.g., data collection tools, study protocol, deidentified data, etc.).

Do you digitally agree to being audio and video recorded during this focus group? (*Individuals cannot participate in this focus group if they do not agree to be audio/video recorded*)

- Yes [Move on to the next question]
- No [Screen out and message shows: You have been removed from the focus group participant pool. Thank you for your time.]

*Do you digitally agree to participate in a focus group where you will discuss your tobacco-related knowledge, perceptions, and behaviors?

- Yes
- No [Screen out and message shows: You have been removed from the focus group participant pool. Thank you for your time.]

Certificate of Confidentiality Statement:

This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT protect your information if a federal, state, or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used for other research if allowed by federal regulations. Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information.

The Certificate of Confidentiality will not be used to stop sharing your information for any purpose you have consented to in this informed consent document, such as allowing project staff to store and share information collected from the focus group.