OMB# 0910-0796
Exp. 12/31/2024

U.S. Food and Drug Administration
Center for Tobacco Product

[Text within brackets will not show to participants]

[Appendix F: In-Depth Interview Adult Consent]

Consent to Participate in Research Study

Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0796. The time required to complete this information collection is estimated to average 90 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRASTAFF@fda.hhs.gov.

Purpose

We are talking to adults all over the United States for a study sponsored by the Center for Tobacco Products at the U.S. Food and Drug Administration (FDA). This research study asks people their thoughts about health behaviors like tobacco use. You have been invited to take part in this study because you said you smoke or used to smoke menthol cigarettes. Approximately 24 people will participate as part of this research study conducted by RTI International. If you agree to participate, you will answer a short survey and then immediately take part in a one-on-one interview. The interview will be conducted online using Zoom, a video and audio platform, so you will be able to see and talk with the interviewer. The discussion will last on average 90 minutes and will be audio recorded (no video recording). A note-taker will also be present and some other members from the research team, including staff from FDA, may observe the online interview to hear your experiences directly from you.

The mission of the FDA is to promote and protect public health. In conducting this study, FDA does not intend to sell tobacco, nor promote, condone, normalize, or encourage its use. The questionnaires, surveys, and messages in this study are not intended to promote, directly or indirectly, other behaviors that may be a gateway to subsequent risky behaviors, such as illegal drug use, binge drinking and smoking.

Risks

There are minimal psychological or social risks to participating in this study. You may or may not feel comfortable answering some of the questions in the interview, and you do not have to answer any questions that you do not want to answer. However, your responses are important because they will help researchers better understand menthol cigarette use.

Benefits

There is no direct benefit to you from participating. However, your responses are very important because they will help researchers understand how people think about health behaviors like tobacco use.

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Voluntary Participation

Your participation in this research study is completely voluntary. If you are eligible and participate in an interview, you will receive a $75 token of appreciation for participating. You can choose not to talk about any topic, and you can stop participating at any time, and you will still receive the token of appreciation._

Use of Information

Information from this study may be published in professional journals or presented at meetings, but no names will ever be used. In the future we may use or share data with other researchers for other studies, but it will not include any personally identifiable information. If we use or share data with researchers for other studies, we will not contact you to ask for your additional informed consent.

Confidentiality

The information that you provide in the study will be handled confidentially. To help ensure your answers are kept private, please complete the interview in a place where no one can hear you.

We have procedures in place that are designed to ensure that your full name will not be connected to your answers. Although there is a chance your answers could be seen by someone who shouldn't have access to it, we're minimizing this risk in the following ways:

- L&E Research, the company coordinating the interviews, will only share your first name, last name, and email address with RTI International.
- RTI will save the interview audio recording, transcription, and notes with a code number. Only RTI maintains a link between code numbers and your first and last name.
- RTI will only share with L&E Research that you have completed the study for the purpose of distributing your token of appreciation.
- All interview data will be kept on a secure RTI server with access only to authorized project staff members for a period of 5 years, after which they will be destroyed.
- RTI International will share interview recordings and deidentified transcripts with FDA. "Deidentified" means that the information that connects your identity to your responses will be removed.

This project is funded by FDA and holds a Certificate of Confidentiality that offers additional legal confidentiality protection. The most important protection is that members of the research team cannot be forced to disclose or provide any of your private identifiable information, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding unless you provide permission. Disclosure of your research information may only occur in limited instances such as:

- You can freely discuss your involvement in this research.
- The researchers cannot refuse requests for information from the FDA, the survey's sponsor.
- In situations involving imminent danger, the law requires the researchers to disclose certain information.

Questions

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If you have any questions about this study, you may call Matthew Eggers of RTI at 919-990-8380, or at 1-800-334-8571, extension 28380. You may also send an email to meggers@rti.org. If you have any questions about your rights as a study participant, you may call RTI's Office of Research Protection at 1-866-214-2043. You can print or take a screenshot of this form if you would like a copy for your records.

Do you agree to participate in a short survey and then participate in the interview for this research study?

1 Yes
2 No

[IF YES, CONTINUE TO INTERVIEW]
[IF NO, GO TO END]

[END]
Thank you for your time.