

OMB No: 0910-0810
Expiration Date: 12/31/2024

YOUNG ADULT INFORMED CONSENT FORM
LCC and Blunt Use Audience Insights Survey

Sponsor / Study Title: RTI International / “Monthly Monitoring Study”

Principal Investigator: (Investigator) Jennifer Duke

Telephone: 919-541-1249 (24 Hour)

Address: RTI International
3040 Cornwallis Rd
Research Triangle Park, NC 27709

Key Information

You have been asked to take part in a national, online study called Your Voice Now. The purpose of this research study is to monitor youth and young adult perceptions and emerging trends in brand and device use for little cigar and cigarillo (LCC) use with and without marijuana (i.e., blunts). RTI International, a non-profit research organization, is surveying approximately 57,000 youth and young adults across the country for this study. RTI will recruit youth and young adults 15 to 24 years old through social media platforms. The self-administered online survey will be used to monitor trends in tobacco use, including products with marijuana. All participants will be screened for eligibility prior to administration of the survey instrument. It will take about 15 minutes for you to complete this survey. If you complete the survey, you will receive a \$5 digital Amazon gift card as a token of appreciation. If you do not complete the survey, you will not receive an Amazon gift card. There will be no charge to you for your participation in this study.

You will not be harmed by being in this study. There is a small chance that you might feel embarrassed or upset by the questions asked in the survey. However, you can respond “prefer not to answer” to any question and may drop out of the survey at any time for any reason. We recommend that you take the survey in a place that is private, to reduce the chance of someone else seeing your responses. Please do not take the survey while driving, and please be prepared to take the survey in one sitting.

It is your choice to take part in this study. There are no direct benefits to you from taking this survey. However, you will be contributing to important research related to tobacco. Your answers will help the U.S. Food and Drug Administration (FDA) stay current about tobacco product use among people your age.

If you are interested in learning more about this study, please continue to read below.

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You will enter your responses to the questions directly into the online survey. If you do not enter any responses for 60 minutes, you will be automatically logged out. This is to protect your privacy, so nobody will be able to see any survey responses on your screen. For the same reason, it is not possible to move backward through the survey. You will not be allowed to re-enter the survey. We will not ask you your name. Some personal information, like your email address and age, will be gathered. Your answers will be labeled with a number instead of your name. This makes it so only study staff will know these are your answers. You may choose not to participate, or you may stop taking the survey at any time without penalty.

The research team understands that the security of online transmissions is not guaranteed due to the risk of interception by third parties, or the possibility of monitoring software installed on research participants' electronic devices. Your identity will not be known in the results of the study. Everything you share will be kept private to the extent allowed by law. Only the authorized study staff will have access to your responses. We are only interested in the combined responses from everyone who is selected to participate, not just one person's answers. Your answers combined with all other responses will be shared with FDA. Your e-mail address or any identifying information will not be shared or associated with any response data. We will not share any information you give us with anyone outside the FDA and RTI study staff. However, your answers could be used for future research studies or distributed to another investigator for future research studies without additional informed consent. If that happens, all identifiable private information will be removed before your answers are shared.

You do not waive any of your rights as a research participant.

The investigator can stop your participation at any time without your consent for the following reasons:

- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

This study is for research purposes only. The only alternative is to not participate in this study. Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

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:
Study Subject Adviser
Advarra IRB
6100 Merriweather Dr., Suite 600

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Columbia, MD 21044

- or call **toll free:** 877-992-4724
- or by **email:** adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser:
Pro00056113.

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Certificate of Confidentiality

This study is covered by a special protection called a Certificate of Confidentiality (CoC). This special protection requires that study staff involved in this study protect your privacy. This means study staff generally cannot provide any information that could identify you to anyone who is not connected with the study. Study 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, study 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 money is being spent; or
- A law requires sharing information (for example, when study staff must report to FDA, or if study staff hear threats of harm to yourself or 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 in this study or your history of tobacco or marijuana use.

I understand the study purpose and process.

Would you like to participate in this survey?

Yes, I want to take the survey.

No, I do NOT want to take the survey.

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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 0910-0810. The time required to complete this information collection is estimated to average 2.5 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.