

ATTACHMENT 4: PROMISING THEMES STUDY ADULT CONSENT

You have been asked to take part in a national, online self-administered study called Promising Themes. The study is being led by Research Triangle Institute (RTI) International, which is a company that does research and evaluation. The survey will ask adults ages 18 to 24 years old their perceptions about various tobacco products including e-cigarettes, cigarettes, little cigars, cigars, cigarillos (LCCs), and smokeless tobacco. Your answers will help with the development of new campaign messages for future FDA media campaigns. It will take about 20 minutes for you to complete this survey.

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.

If you decide to take the survey, you will receive a \$5 digital Amazon gift card as a token of appreciation. There are no additional benefits from completing the survey.

It is your choice to take part in this study. You will enter your responses to the questions directly into the online survey. If you do not enter any responses for 10 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 RTI staff will know these are your answers. You may stop taking the survey at any time without penalty. 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 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 will be shared with the FDA but not your personal information. We will not share any information you give us with anyone outside the FDA and RTI study teams.

If you have any questions about the study, you may contact the study team through Jennifer Duke of RTI International at (800) 608-2955 or yourvoicenow@rti.org.

This study is covered by a special protection called a Certificate of Confidentiality (CoC). This special protection requires that staff involved in this study protect your privacy. This means staff generally cannot provide your name or any other information that could identify you, to anyone who is not connected with the study. Staff cannot share this information in court or during other legal proceedings, unless you or your parent agree, even if there is a court order for the information. However, in other settings, 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 staff must report to FDA, or if

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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.

If you choose YES, we will email you a copy of the form.

Paperwork Reduction Act Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting burden for this information collection has been estimated to average 2 minutes per response to complete the Informed Consent 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.