

[Text within brackets will not show to participants]

**[Appendix A:
Online Survey Young Adult Consent]
Consent to Participate in Research Study**

We are talking to youth and young 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). 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. This research study asks people about nicotine and tobacco products. About 2,004 people are being asked to take a survey as part of this research study conducted by RTI International. The survey will take about 15 minutes. You may only take the survey one time.

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 these surveys, such as those about tobacco use. There is no direct benefit to you from participating. However, your responses are very important because they may help researchers understand how people interpret tobacco product information.

The information that you provide in the study will be handled confidentially. To help ensure your answers are kept private, please complete the surveys in a place where no one can look over your shoulder and view your answers. Do not complete the survey while driving.

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

- RTI will identify you with a code number when we collect your survey responses. Only RTI maintains a link between code numbers and personally identifying email address and date of birth. RTI will use this information for the purposes of fraud detection and distributing incentives, and the link between personally identifying information and survey responses will be broken once the study is complete and incentives have been distributed. Although we cannot guarantee that no one outside of the study team can reidentify this data, it is highly unlikely that this will occur. If a security breach were to occur, all participants will be told about the breach, how serious the breach is, and any bad things that have happened or could happen because of the breach.
- In order to receive the gift card incentive, you must provide an email address. The email address will only be used for the purpose of sending your incentive (through Creative Group Inc.) and will not be otherwise sold or shared.
- RTI International will deliver a deidentified dataset to FDA. "Deidentified" means that the information that connects your identity to your responses will be removed. The deidentified dataset will be kept on a secure RTI server with access only to authorized project staff members.

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 your deidentified data with other researchers for other studies. If we do so, we will not contact you to ask for your additional informed consent.

Your participation in this research study is completely voluntary. If you don't want to take the survey, that is okay. If you get to a question on the survey that you do not want to answer, you can skip it. You can drop out of the survey at any time for any reason by closing your Internet browser.

If you are eligible and complete the survey, you will receive a \$5 gift card at the email address you provide within 1-2 weeks as a token of our appreciation. If you stop participating before you complete the survey, you will not receive a gift card. Responses will be verified prior to issuing the gift card; If we find that you have completed the survey more than once, you may not receive a gift card.

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

The Institutional Review Boards (IRB) at RTI International and FDA have reviewed this research. An IRB is a group of people who are responsible for ensuring that the rights of participants in research are protected. The IRB may review the records of your participation in this research to ensure that proper procedures were followed.

If you have any questions about this study, you may call Youn Lee of RTI at 919-541-8735, or at 1-800-334-8571, extension 28735. 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. If you are a tobacco user, or have a friend or family member who is a tobacco user, and you would like information on how to quit, please visit <https://smokefree.gov/>.

Do you agree to participate in the survey?

- 1 Yes
- 2 No

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 2.5 minutes per response (the time estimated to read, review, respond). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRASStaff@fda.hhs.gov.

[PROTOCOL TITLE: Nicotine Education Project

RTI PRINCIPAL INVESTIGATOR: Youn Lee

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[IF YES, GO TO SURVEY]

[IF NO, GO TO END]

[END]

Thank you for your time.