

## **Appendix I: Online Survey Youth Assent**

We are talking to teenagers all over the United States for a study sponsored by the Center for Tobacco Products at the U.S. Food and Drug Administration (FDA). Your parent or legal guardian has given permission for you to take two surveys. This research study asks people about the chemicals in cigarettes and cigarette smoke. About 4,500 people are being asked to take these surveys. The first survey is a screening survey that will take about 3 to 5 minutes and determine if you are eligible for a longer survey that will take about 20 minutes.

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 will help researchers understand how people interpret tobacco product information.

Your personal information will never be linked to your responses. We will not share any information you give us with anyone outside the research team, and all your answers will be kept private. Any forms for the project that have your name or anything that could identify you will be kept in a locked file cabinet. Except for this consent form, these forms will be destroyed once the project ends. We are required to store this consent form for at least 3 years. Information from this study may be published in professional journals or presented at meetings, but no names will ever be used.

We will try to protect the information you provide. In all studies, there is a chance that privacy could be broken because of an accidental error or a security breach. If this happens, you will be told about the extent of the breach, any damages, and future potential risks and given contact information if you have questions.

Every effort will be made so that no one will be able to know how you answered the questions, not even your parents. Your answers will be combined with answers of many others and reported in a summary form. However, protection of your information cannot be guaranteed. To help ensure your answers are kept private, please complete the survey in a place where no one can look over your shoulder and view your answers.

Your participation in this research study is completely up to you. If you don't want to take the screening survey or longer survey, that is okay. If you get to a question you don't want to answer, you can skip it. You can also drop out of the surveys at any time for any reason. If you participate in the study, your parent or guardian's Global Test Market account will be credited with the LifePoints stated in the invitation.

This research is covered by a special protection (called a Certificate of Confidentiality) from FDA. This special protection requires that researchers involved in this study protect your privacy. This means researchers generally cannot provide your name or any other information that could identify you, to anyone who is not connected with the research. Researchers 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, researchers may share study information that could identify you if:

- you and your parent 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 research money is being spent; or
- a law requires sharing information (for example, when researchers must report to FDA, or if researchers 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 research study or your history of tobacco use.

The Institutional Review Board (IRB) at RTI International and the Research Involving Human Subjects Committee at FDA has 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 Jessica Pepper of RTI at 919-316-3180, or at 1-800-334-8571, extension 23180. 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.

**Do you agree to participate in the study?**

- 1 Yes
- 2 No

[IF YES, GO TO SCREENER]

[IF NO, GO TO END]

**END**

Thank you for your time.

**Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 3 minutes per response to complete the screener (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](mailto:PRASStaff@fda.hhs.gov).**