

## **Appendix H: Online Survey Parental Permission**

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). This research study asks people about the chemicals in cigarettes and cigarette smoke. About 4,500 people are being asked to take two surveys as part of this research study conducted by RTI International. The first survey for your child is a screening survey that will take about 3 to 5 minutes and determine if your child is eligible for a longer survey that will take about 20 minutes.

We need permission from a parent or guardian before we survey your child. Your child will be asked about their experiences with tobacco products, and after viewing a list of cigarette ingredients, will be asked questions about the information presented to them. Your child will take the surveys online.

There are minimal psychological or social risks to participating in this study. Your child 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 your child from participating. However, your child's responses are very important because they will help researchers understand how people interpret tobacco product information.

Your child's personal information will never be linked to his or her responses. We will not share any information you or your child gives us with anyone outside the research team, and all your child's answers will be kept private. Any forms for the project that have your or your child's name or anything that could identify you or your child 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 your child provides. 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 your child answered the questions. Your child's answers will be combined with answers of many others and reported in a summary form. However, protection of your child's information cannot be guaranteed. Your child will be instructed on the introductory screen to complete the surveys in a place where no one can view their answers.

Your child's participation in this research study is completely voluntary. If your child doesn't want to take the screening survey or longer survey, that is okay. If your child gets to a question they do not want to answer, they can skip it. Your child can drop out of the survey at any time for any reason. If your child participates in the study, your 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 child's privacy. This means researchers generally cannot provide your child's name, or any other information that could identify your child,

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 child agree, even if there is a court order for the information. However, in other settings, researchers may share study information that could identify your child if:

- you or your child 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 others or reports of child abuse).

The Certificate of Confidentiality does not prevent you and your child from sharing any personal information or information about your child's involvement in this study with others. For example, you can share that your child is in this research study or your child's 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.

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.

**1. What is the age of the child you will invite to participate in this survey?**

\_\_\_\_ years old

[IF AGE IS NOT 13-17 GO TO END]

**2. Do you give permission for your child to participate in the study?**

- 1 Yes
- 2 No

[IF YES, GO TO P\_INTRO]

[IF NO, GO TO END]

**P\_INTRO**

It is important that your child be allowed to answer the questions in privacy. From this point on, your child should be able to read and answer all questions on his or her own. Press "Next" when your child is ready to begin. [GO TO ASSENT]

**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 for your child 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).**