[Text within brackets will not show to participants]

[Appendix H:
Online Survey Parental Permission]

Parental Permission for Youth to Participate in Research Study

We are talking to teenagers ages 13-17 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 2 surveys as part of this research study conducted by RTI International. The first survey for your child (ages 13-17) 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.

The information that your child provides in the study will be handled confidentially. To help ensure your child's answers are kept private, please have your child complete the surveys in a place where no one can look over his or her shoulder and view his or her answers.

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

- The surveys will not ask for your child's name. Lightspeed Research, the company hosting this survey, will identify your child only with a code number. Your name, your child's name, and any other information that could directly identify you or your child will not be part of this study's dataset. Only Lightspeed Research maintains a link between code numbers and personally identifying panel profile information for Lightspeed Research panelists. Although we cannot guarantee you that no one can reidentify this data, it is highly unlikely that this will occur.
- If you are a panelist for one of Lightspeed Research's partner panels, the partner panel will never have access to your child's survey responses. Lightspeed Research will only share code numbers with partner panels for the purpose of distributing your compensation.
- Lightspeed Research will not share any personally identifiable information with RTI International. RTI International will receive a deidentified dataset from Lightspeed Research. "Deidentified" means that the information that connects your identity to your child's responses will be removed. The deidentified dataset will be kept on a secure RTI server with access only to authorized project staff members.

- RTI International will deliver a deidentified dataset to FDA.

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 child's 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 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. Determining your child's eligibility for the longer survey requires that he or she answer certain screening questions. If your child chooses not to answer one or more of those screening questions, your child will be routed out of the screening survey and cannot take the longer survey. Based on your child's answers to the screening questions, if your child is eligible for the longer survey, he or she will be routed directly to that survey.

If your child gets to a question on the longer survey that he or she does not want to answer, he or she can skip it. Your child can drop out of the screener or longer survey at any time for any reason by closing the Internet browser. Even if your child is not eligible for the longer survey or drops out of the longer survey, your account will be credited with the compensation stated in the invitation; in this circumstance, it may take up to 90 days to receive the compensation.

This project is funded by FDA and holds a Certificate of Confidentiality that offers additional legal confidentiality protections. The most important protection is that members of the research team cannot be forced to disclose or provide any of your child's private identifiable information, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding unless you provide permission. Disclosure of your child's research information may only occur in limited instances, such as:

- You can freely discuss your child's 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 child's 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 child's rights as a study participant, you may call RTI's Office of Research Protection at 1-866-214-2043. You can take print or take a screenshot of this form if you would like a copy for your records.

1. **What is the age of the child you will invite to participate in this study? If you have more than one child between the ages of 13-17, we recommend choosing the one who is currently available to take the survey.**

   _____ years old

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

2. **Do you give permission for your child to participate in the screening survey to determine your child's eligibility and (if they are eligible) do you also give permission for your child to participate in the longer survey?**

   1 Yes
   2 No

[IF YES, GO TO P_INTRO]
[IF NO, GO TO END]

[P_INTRO]

Now we will be asking your child screening questions to see if he or she is eligible for a longer survey. If eligible, he or she will be directed to begin the longer survey. It is important that your child be allowed to answer all questions in privacy. From this point on, your child should be able to read and answer all questions on his or her own. Please bring your child to this computer, and 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 PRAStaff@fda.hhs.gov.