[PROTOCOL TITLE: Measuring Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents (HPHCs) in Tobacco Products

RTI PRINCIPAL INVESTIGATOR: Jessica Pepper

Version 7-27-20]

OMB# 0910-0880 EXP: 11/30/2022

[Text within brackets will not show to participants]

[Appendix G: Online Survey Adult Consent] Consent to Participate in Research Study

We are talking to 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). 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 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.

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.

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:

- Lightspeed Research, the company hosting this survey, will identify you only with a
 code number. Your name and any other information that could directly identify you
 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 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 survey responses. Lightspeed Research will only share code numbers (of respondents who complete the longer survey) 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 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 deidentified data with other researchers for other studies. If we do so, we will not contact you to ask for your additional informed consent.

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Your participation in this research study is completely voluntary. If you don't want to take the screening survey or longer survey, that is okay. Determining your eligibility for the longer survey requires that you answer certain screening questions. If you choose not to answer one or more of those screening questions, you will be routed out of the screening survey and cannot take the longer survey. Based on your answers to the screening questions, if you are eligible for the longer survey, you will be routed directly to that survey.

If you get to a question on the longer survey that you do not want to answer, you can skip it. You can drop out of the screener or longer survey at any time for any reason by closing your Internet browser. If you are eligible and complete the longer survey, your account will be credited with the compensation stated in the invitation. If you are not eligible or stop participating before you complete the longer survey, you will not be credited with any compensation.

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 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. You can print or take a screenshot of this form if you would like a copy for your records.

Do you agree to participate in the screening survey to determine your eligibility and (if you are eligible) to participate in the longer survey?

1 Yes

2 No

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 PRAStaff@fda.hhs.gov.

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Constituents (HPHCs) in Tobacco Products

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

[END]

Thank you for your time.

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