Monthly Monitoring Study
Supporting Statement: Part B

B. STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

The one-time actual burden figures are listed in the tables in the Part A Supporting Statement (p. 11 – 12).

For this study, we will obtain a final sample size of 21,000 youth and young adults. Data collection will be split among two surveys. We plan to obtain approximately 18,000 survey completes among youth and young adults ages 15–24 who are susceptible to, or currently use vaping products. The survey will be repeated with a new cross-sectional sample each month for 12 months. Respondents will be allowed to complete additional, cross-sectional surveys after 6 months. We will also survey approximately 3,000 youth and young adults ages 15 to 24 years who are susceptible to, or currently use cigar products. The survey will be repeated with a new cross-sectional sample four times a year. Respondents will be allowed to complete an additional, cross-sectional survey after 6 months. As this study is considered part of formative research for campaign development and planning, these methods are not intended to generate nationally representative samples or precise estimates of population parameters. The sample is designed primarily to monitor perceptions about vaping products and little cigars or cigarillos (LCCs). The results of the vaping surveys and the LCC surveys will be used to inform specified recommendations around the U.S. Food and Drug Administration's (FDA's) public education programs' impact and effectiveness in reducing tobacco-related death and disease.

Sampling Methods

The study sample will be comprised of participants between the ages of 15 and 24 years who: (1) are susceptible to, or currently use vaping products; or (2) are susceptible to, or currently use LCCs. This study is considered part of formative research for campaign development and planning, and these methods are not intended to generate nationally representative samples or precise estimates of population parameters. The sample is designed primarily to provide information on the perceptions and trends in tobacco and vaping.

Participants will be recruited through targeted social media advertising on Facebook and Instagram. After clicking on the advertisement, participants will be directed to the screener (Attachments 1 and 2). After completing the screener, participants will be asked to include a personal email address to receive their token of appreciation. The online screener will take approximately 2.5 minutes to complete. Screener instructions note that respondents may only complete the surveys one time. The screener does not include questions that are especially sensitive or that we anticipate will be upsetting to those who read or complete it. The primary purpose of the online screener is to screen out participants that are not eligible to complete one of the two online surveys. The Hispanic identification questions included in the screener are

necessary to determine differences in behavior among subgroups that will be informative for FDAs campaign development (i.e., understanding behaviors by race/ethnicity will allow FDA to tailor campaign messages). Individuals may decline to participate in the online screener if they wish. Individuals also must acknowledge that they read the Facebook or Instagram Authorization Statement depending on the social media website from which they access the survey. The Authorization Statement describes the information that could be learned about the participant as part of the process that Facebook and Instagram use to make sure that they have a real account. Facebook and Instagram will not share any other information about their account with RTI International (RTI).

Sample Size

To obtain a final sample of 21,000 youth and young adults ages 15–24, we will need to screen approximately 42,000 potential participants for both surveys.

2. Procedures for the Collection of Information

This section describes the procedures for the survey data collection. The survey will be conducted via a web-based survey disseminated by RTI International. All surveys will be conducted using a self-administered, online survey. To be eligible, the youth (ages 15–17) must give their assent (Attachments 3 and 4), the young adults (18-24) must give their consent (Attachments 5 and 6), and participants must be susceptible to, or currently use vaping products or LCCs. The screeners are included in Attachments 1 and 2. Links to the survey instruments (Attachment 1 for the vaping instrument and 2 for the LCC instrument) will only be provided to participants after they complete the screener and give their assent or consent. As a check for validity, the birthdate in the screener and the age that the participant completes as part of the instrument must match one another for the participant to be eligible.

Generic 0910-0810 is covered underneath an approved umbrella PIA. FDA IRB will not be the IRB of record and will defer to RTI IRB's policies and oversight. This study has received a "not human research" determination from RTI's Institutional Review Board and will not be conducted under their oversight. The study team is committed to the protection of human subjects and the privacy and security of participant data, and we engaged RTI's Privacy Officer and Risk Management team to assess the risks to participants and our risk mitigation approach. For this study, we are not collecting any data, including personally identifiable data, from parents. We consulted with the RTI Privacy Officer and with Risk Management and based on the content of the online survey and study design, received confirmation that it is permissible to contact participants ages 15 to 17 without parental permission. Eligible youth who are 15 to 17 years old will not require parental permission and will therefore encounter the assent language once they are routed to the survey. We recognize that some of the behaviors we are asking about are not legal for some respondents (e.g., respondents under 21 in non-recreational marijuana use states, respondents under 18 who use tobacco). The central purpose of this study, which is to provide FDA with public health surveillance on tobacco product use among youth and young adults, cannot be achieved without directly recruiting and surveying youth ages 15 to 17. Since the surveys focus on perceptions and trends in tobacco and vaping, which requires questions about marijuana use, it is anticipated that the parents of some eligible participants would refuse to grant

permission for their child to participate. Further, the youth may not answer questions accurately if they feel their parents are somehow observing or approving their participation and requiring parental permission would likely yield a lower response rate and impede the ability to carry out this study. The youth participants' responses will not be linked to their names or email addresses. RTI's Privacy Officer and Risk Management allowed us to waive parental permission based on the nature of this study, the lack of linkage between youth respondents answers to the online survey and their name, as well as the need for accurate and truthful responses from this population.

Consistent with the Federal Children's Online Privacy Protection Act (COPPA), we will screen out youth under the age of 15. This study poses only a minimal risk to participants and would not adversely affect their rights or welfare in any foreseeable way.

Summary of Protocol

The list of study procedures is as follows:

Monthly Media Study participants recruited through social media

1. Participants are recruited through targeted social media advertising on Facebook and Instagram. As part of the recruitment process, participants will be asked to provide their email address, which may be their social media account username. Email address is required for fraud prevention and respondents are notified at the beginning of the survey that we will collect this information. No other social media profile identifiers will be collected.
2. After clicking the link in one of the social media advertisements, participants will be directed to the screener link.
3. Participants will complete the screener and, if they qualify, will be directed to the one of the online surveys.
4. Eligible participants who provide their email address upon completing one of the monthly monitoring online surveys will receive one $5 digital gift card from Amazon as compensation for their time after we have confirmed that they have only taken the survey one time in the past six months.
5. We will work with a distribution vendor, Creative Group, Inc., by purchase order to send a thank you message via email along with a digital gift card to participants who complete one of the online surveys.

E-mail addresses will be collected in the Qualtrics survey platform and stored in an isolated survey that will contain a RTI-assigned unique ID and email address. IP address will be collected in the survey platform in an isolated survey that contains IP address, RTI-assigned unique ID, and screener responses. Date of birth will be collected in an isolated survey that will contain a RTI-assigned unique ID and date of birth. Responses to the body of the survey will be collected in the Qualtrics survey platform and stored in an isolated survey. IP address, e-mail address, and date of birth will not be collected in the same file.

All four survey data files (IP address, e-mail, date of birth, and survey responses) will be downloaded separately from Qualtrics (which requires a password). Since the Federal

Information Processing Standards (FIPS) 199 does not permit access to the internet (and downloading the data from Qualtrics requires an internet connection), the four files will be downloaded to the secure RTI study share drive and stored on the study share drive for no more than 24 hours after download. Study staff will be given as-needed access to the data files on the share during that 24-hour period to conduct fraud detection procedures, at which point data from the individual will be combined to check for fraudulent responses.

Once fraud detection procedures have been completed (within 24 hours after download), we will send a password protected file of just the e-mail addresses to Creative Group. We will then send the password to Creative Group in a separate e-mail. Password protected/encrypted files with just e-mail addresses will be stored on the share drive until the study is completed. After completion of the study, all files containing e-mail address and/or IP address will be moved to the Federal Information Processing Standards (FIPS) 199. Once these files have been transferred any files on the study share that contain e-mail, date of birth, and/or IP addresses will be deleted. The file containing participant ID (but not e-mail address, date of birth, and/or IP address) and the survey responses will remain on the study share drive for analysis. At the completion of data collection, all response data will be deleted from the survey platform (Qualtrics) and remain only on RTI's secure shared drive and Federal Information Processing Standards (FIPS) 199.

At the end of data collection, a member of the project staff will export the data from the survey and out of the ESN, saving them directly onto the project share drive. Only RTI project staff directly involved in programming, sampling, recruitment, or analysis will have access to the survey data or sampling frame. No respondent identifiers will be contained in reports to FDA, and results will only be presented in aggregate form.

To reduce the potential of participants completing multiple surveys and to reduce non-U.S. based youth from completing surveys, IP addresses from outside of the U.S. will be blocked from taking the screener. Additionally, we may maintain a list of IP addresses from which we receive repeated fraudulent activity as defined above. IP addresses appearing on this list may be blocked from accessing the screener or main survey. We also block VPNs with an IP address from a potential spoofing site.

Unusual Problems Requiring Specialized Sampling Procedures

No specialized sampling procedures are involved.

Use of Periodic Data Collection Cycles to Reduce Burden

The survey to monitor perceptions about vaping products, little cigars or cigarillos (LCCs), and other emerging tobacco products will be repeated with a new cross-sectional sample each month for 12 months. Respondents will be allowed to complete additional, cross-sectional surveys after 6 months. The survey to monitor trends in LCC use among youth and young adults ages 15 to 24 years will be repeated with a new cross-sectional sample four times a year. Respondents will be allowed to complete an additional, cross-sectional survey after 6 months.

3. Methods to Maximize Response Rates

The ability to obtain the cooperation of potential respondents in the survey will be important to the success of this study. RTI International will minimize the non-response rate by employing the following measures:

1. Employ targeted advertising to best reach the desired sample
2. Provide a token of appreciation in the form of a $5 digital gift card from Amazon to participants who complete and submit the survey

We will use targeted advertising on Facebook and Instagram to reach the target population. We estimate that the survey will take 12 minutes to compete. As a token of appreciation, participants recruited through social media who complete and submit the survey will receive a $5 digital gift card from Amazon. As participants often have competing demands for their time, a token of appreciation for participation in research is warranted. The use of a token of appreciation treats participants justly and with respect by recognizing and acknowledging the effort participants expend to participate. Numerous empirical studies have also shown that a token of appreciation can significantly increase response rates in cross-sectional studies and reduce attrition in longitudinal studies (e.g., Abreu & Winters, 1999; Castiglioni, Pforr, & Krieger, 2008; Shettle & Mooney, 1999; Singer, 2002). Additionally, evidence indicates that at-risk and multicultural populations may be particularly difficult to recruit and retain in health research (Hooven, Walsh, Willgerodt, & Salazar, 2011; Zand et al., 2006; Post, Gilljam, Bremberg, & Galanti, 2012; Patel, Doku, & Tennakoon, 2003; Siddiqui, Flay, & Hu, 1996; Giuliano et al., 2000; Murthy, Krumholz, & Gross, 2004), but that the use of a token of appreciation can be an effective means of recruiting and retaining participants from these populations (Martinson et al., 2000; Booker, Harding, & Benzeval, 2011; Caldwell, Hamilton, Tan, & Craig, 2010; Walter, Burke, & Davis, 2013).

4. Tests of Procedures or Methods

RTI International will conduct rigorous internal testing of the online survey instruments prior to fielding. Survey testers will review the online test version of the instrument that we will use to verify that instrument skip patterns are functioning properly, delivery of the $5 gift card as a token of appreciation is working properly, and that all survey questions are worded correctly and are in accordance with the instrument approved by OMB.

5. Individuals Involved in Statistical Consultation and Information Collection

The following individuals inside the agency have been consulted on the design of the study plan, audience questionnaire development, or intra-agency coordination of information collection efforts:

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