U.S. Food and Drug Administration
Center for Tobacco Products
Monthly Monitoring Study: Little Cigar, Cigarillo, and Blunt Use Audience Insights Survey
OMB Control Number 0910-0810
Generic IC 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. 9-10).

For this study, we will obtain a final sample size of 1,550 youth and young adults, ages 15-24 years, who are susceptible to using blunts or who have used blunts. 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 study is designed primarily to assess use and perceptions about little cigars or cigarillos (LCCs) with and without marijuana (i.e., blunts). The results of the survey will be used to inform specified recommendations around the U.S. Food and Drug Administration's (FDA's) public education programs aimed at 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 are: 1) susceptible to blunt use or 2) blunt users.

Participants will be recruited through targeted social media advertising on social media platforms, such as Facebook and Instagram. After clicking on the advertisement, potential participants will be directed to the screener (Attachment 1). 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 purpose of the online screener is to screen out participants that are not eligible to complete the survey.

The race and ethnicity identification questions included in the screener are necessary because the study is designed to oversample those who identify as African American or Black. As such, we will need to collect race and ethnicity data in the screener. Further, collecting this information is important to assess differences in behaviors and perceptions among subgroups that will be informative for FDAs campaign development (i.e., understanding behaviors by race/ethnicity will allow FDA to tailor campaign messages).

Gender identity and sexual orientation
Collection of detailed demographic information, including a more expansive gender identity and sexual orientation question, are necessary in order to assess disparities in tobacco use and possible differences in tobacco and marijuana use across different subpopulations. Decades of

research has shown significant disparities in tobacco use by gender identity (e.g., Johnson et al, 2019; Delahanty et al, 2019), and sexual orientation (e.g., Johnson et al, 2019; McCabe et al., 2018). Therefore, collecting detailed information on these demographic characteristics will allow us to measure these differences with the goal of reducing these disparities. As multiple studies of youth and young adults have reported approximately 12-15% of the sample identified as gender non-conforming/non-binary (e.g., The Human Rights Campaign 2018 LGBTQ+ Youth Report; The Trevor Project 2020 National Survey on LGBT Youth Mental Health; CTP's evaluation of *This Free Life* campaign), including gender non-conforming/non-binary response options is necessary to identify and assess tobacco use and campaign effectiveness among this population. Gender identity questions with genderqueer/gender non-conforming/non-binary response options have been approved by OMB for ExPECTT FU3 and for RESPECT (0910-0808) as well as more recently for for ExPECTT is 0910-0753.

Furthermore, data the 2021 National Youth Tobacco Survey demonstrates that teens who are sexual or gender minorities have higher cigar (large cigar, little cigar, or cigarillo) use compared to heterosexual teens. While 4.9% of heterosexual teens reported ever use of cigars, 7.9% of gay/lesbian teens, 5.5% of bisexual male teens, and 10.2% of transgender teens reported ever cigar use. Including survey items on sexual orientation and gender identity is necessary to identify our target audience for education activities and address disparities in cigar use.
Along with the extensive and increasing body of literature showing tobacco use disparities among LGBTQ+ populations, the White House issued the Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals which includes obligations for federal agencies to collect SOGI data. The order states that, "advancing equity and full inclusion for LGBTQI+ individuals requires that the Federal Government use evidence and data to measure and address the disparities that LGBTQI+ individuals, families, and households face." It also states that federal agencies must "describe disparities faced by LGBTQI+ individuals that could be better understood through Federal statistics and data collection" (White House, 2022). Given that teens who are sexual or gender minorities have higher use of cigar products compared to heterosexual and cisgender teens, it's important for us to capture both sexual and gender identity information to accurately identify our target audience for education activities and address disparities in cigar product use.

The project team will not conduct or report on statistical analysis for demographic groups for which there is insufficient statistical power.

Individuals may decline to participate in the online screener if they wish. Individuals also must acknowledge that they read the applicable social media platform Authorization Statement, based 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 social media platforms use to make sure that they have a real account. The social media platforms will not share any other information about their account with RTI International (RTI).

Sample Size
To obtain a final sample of 1,550 youth and young adults ages 15–24, we will need to screen approximately 10,000 potential participants.

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. All surveys will be conducted using a self-administered, online survey. To be eligible, youth (ages 15–17) must give their assent (Attachment 2), young adults (18-24) must give their consent (Attachment 3), and participants must be susceptible to blunt use or report blunt use. The screener is included in Attachment 1. Links to the survey instruments 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.

The study team is committed to the protection of human subjects and the privacy and security of participant data. Generic 0910-0810 is covered underneath an approved umbrella PIA. FDA's Institutional Review Board (IRB) will not be the IRB of record and will defer to Advarra IRB's policies and oversight. For this study, we are not collecting any data, including personally identifiable data, from parents. We received a waiver of parental permission from Advarra IRB. 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., marijuana use; tobacco use for those under age 21). The central purpose of this study, which is to provide FDA with insights into youth tobacco use, cannot be achieved without directly recruiting and surveying youth ages 15 to 17. Since the surveys focus on use and perceptions of blunts, 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 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. Advarra IRB 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:

1. Participants are recruited through advertising on social media platforms, such as 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 (Attachment 1).
3. Participants will complete the screener and, if they qualify, will be directed to the Assent (Attachment 2) or Consent form (Attachment 3) and then the online survey (Attachment 1).
4. Eligible participants who provide their email address upon completing the survey will receive one $5 digital gift card as a token of appreciation for their time after we have confirmed that they have only taken the survey one time.
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 the online survey.

E-mail addresses will be collected in the Qualtrics survey platform and stored in an isolated survey that will contain an 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 an 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. RTI 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), RTI will send a password protected file of just the e-mail addresses to Creative Group. RTI 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 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 FIPS 199. No PII will be shared with FDA.

At the end of data collection, a member of the RTI project staff will export the data from the survey and out of the FIPS 199, 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, results will only be presented in aggregate form, and RTI will deidentify data before delivering to FDA.

To reduce the potential of participants completing multiple surveys and to reduce non-U.S. based youth/young adults 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 Virtual Private Networks (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
This survey will be conducted only one time.

3. Methods to Maximize Response Rates

The ability to obtain the cooperation of potential participants in the survey will be important to the success of this study. RTI 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 to participants who complete and submit the survey

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).

Inclusion of a modest token of appreciation has resulted in studies that had full recruitment, diverse samples, and timely data collection. For example:

- The CTP Media Tracking study (OMB Control Number 0910-0810) was approved with a $5 token of appreciation for a 17-minute survey.
- The CTP Monthly Monitoring Study (OMB Control Number 0910-0810) was approved with a $5 token of appreciation for a 12-minute survey and with a similar target population.

- The CTP Quantitative Study of Tobacco Facts Designed to Inform Youth Tobacco Prevention Messaging (OMB Control Number 0910-0810) was approved with a $10 token of appreciation for a 20-minute survey with a similar target population.
- The CTP Quantitative Study of Tobacco Facts Designed to Inform Youth Tobacco Prevention Messaging conducted in Spring 2020 for new FDA ads (OMB Control Number 0910-0810) was approved with a $10 token of appreciation for a 20-minute survey with a similar target population. The study was fully recruited and completed on time.

4. Tests of Procedures or Methods

RTI 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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