

**U.S. Food and Drug Administration
Center for Tobacco Products
OMB Control No. 0910-0810**

**Monthly Monitoring Study: Little Cigar, Cigarillo, and Blunt Use Audience Insights Survey
Supporting Statement Part A: Summary**

- The goal of this study is to assess youth and young adult use of and perceptions around blunt and other little cigar and cigarillo (LCC) use to inform future CTP public education programs.
- The target audience for this study is youth and young adults ages 15 to 24 years in the United States who are: 1) susceptible to blunt use or 2) blunt users. Given the high prevalence of blunt use among African American/Black populations, the study design will include oversampling of youth and young adults who identify as African American or Black.
- RTI will recruit participants through social media advertisings (e.g., Facebook, Instagram) and collect data via self-administered online surveys.
- Results of the survey will help CTP better understand:
 - The relationship between blunt use and use of other tobacco products (e.g., LCCs with tobacco, cigarettes, nicotine vapes) and marijuana.
 - The sociocultural context of blunts use
 - Brands of LCCs or cigar wrappers used to make blunts
 - Perceptions around the harm and addictiveness of blunts
 - Beliefs about blunt use that could inform CTP public education efforts
- **REQUESTED APPROVAL DATE: 8/19/2022**

Study Materials (attached):

Attachment 1. Screener and Survey

Attachment 2. Youth Assent

Attachment 3. Young Adult Consent

**U.S. Food and Drug Administration
Center for Tobacco Products
Monthly Monitoring Study: Little Cigar, Cigarillo, and Blunt Use Audience Insights Survey**

OMB Control No. 0910-0810

Generic IC Supporting Statement Part A

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

This information collection is in support of the U.S. Food and Drug Administration’s (FDA) Center for Tobacco Products (CTP) efforts to develop public education content aimed at preventing use of little cigars and cigarillos (LCCs).

According to the 2020 National Youth Tobacco Survey (NYTS), little cigar and cigarillo (LCC) products continue to be the top combustible tobacco product used by youth (3.5% for LCCs compared to 3.3% for cigarettes) and the second most-used tobacco product (Gentzke et al. 2020). Moreover, there is also a persistent and well-documented trend of disproportionate use of LCCs among youth of color (Wang et al. 2021 and Gentzke et al. 2020).

Cigarillos are the most popular LCC product sold in the U.S. (X. Wang et al., 2021). Research has shown that among youth and young adults, cigarillos are most often used as blunts (where the tobacco filler is removed and replaced with marijuana) as well as co-used with blunts (Cohn et al. 2016). Further, research has shown that blunts are disproportionately used by Black youth and young adults and particularly in urban areas (Antognoli et al., 2018; Giovenco et al., 2018; Rolle et al., 2015).

As a way to reduce the enormous public health burden of tobacco, the Family Smoking Prevention and Tobacco Control Act has given the FDA the authority to take action to protect children, encourage smokers to quit, and reduce tobacco-related disease and death. The law also enables FDA to educate the public, especially young people, about the dangers of tobacco products. Research shows that public education mass media campaigns can be used to change attitudes and beliefs about tobacco use and reduce smoking prevalence. In fact, the Centers for Disease Control and Prevention (CDC) considers mass media campaigns to be a “best practice” for tobacco control.

In an effort to inform specified recommendations around FDA’s public education programs aimed at reducing tobacco-related death and disease, more research is needed to understand use and perceptions of LCCs, and particularly their use as blunts, so that FDA can develop new public education programs that resonate with youth and young adults who are most at risk for use. The purpose of this study is to collect primary data to better understand use and perceptions of blunt and LCCs among youth and young adults ages 15-24 in the U.S.

2. Purpose and Use of the Information

RTI International (RTI) will conduct online surveys with youth and young adults in the United States recruited through advertisements on social media (e.g., Facebook, Instagram) to assess use and perceptions of LCCs and blunts. As soon as approvals are received, we will begin data collection for a national, online self-administered survey of up to 1,550 participants ages 15-24. The survey will include questions about LCC and other tobacco product use to allow the study team to better understand co-use behaviors. The survey will take approximately 15 minutes to complete per participant. Study results will be used to inform specified recommendations around FDA's public education programs aimed at reducing tobacco-related death and disease.

The study aims to answer the following questions:

- o What is the relationship between blunt use and use of other tobacco products (e.g., LCCs with tobacco, cigarettes, nicotine vapes) among youth/young adults?
- o What are the sociocultural contexts of blunts use? Where are youth/young adults using blunts? Who are they using them with? What are their reasons for use?
- o What brands of LCCs or cigar wrappers are commonly used to make blunts?
- o What are youth/young adults' perceptions around the harm and addictiveness of blunts?
- o What beliefs related to blunt use are held by youth/young adults?

3. Use of Information Technology and Burden Reduction

The study will be conducted using a web-based survey that is self-administered on personal computers or web enabled mobile devices. This study will rely on web-based survey data collection to collect primary data to assess youth and young adult use and perceptions of LCCs and blunts. Using an online survey allows the respondent to be candid with their responses. This increases accuracy of the data because respondents provide more honest responses than when other types of data collection methods are employed, especially when it is clear that the answers will remain private. In addition, using a survey will allow for more participants to respond in a cost-effective and timely manner. The self-administered, web-based survey permits greater expediency with respect to data processing and analysis (i.e., a number of back-end processing steps, including coding and data entry). Data are transmitted electronically, rather than by mail. These efficiencies save time due to the speed of data transmission, as well as receipt in a format suitable for analysis. An added benefit is increased data protection by limiting the amount of personally identifiable information (PII) collected from participants, reducing the risk of data security issues. Finally, as noted above, this technology permits respondents to complete the survey in privacy. The use of a more private data collection method makes reporting potentially embarrassing or stigmatizing behaviors (e.g., marijuana use) less threatening and enhances response validity and response rates.

4. Efforts to Identify Duplication and Use of Similar Information

Given disproportionate use of both blunts and LCCs among Black/African American youth and young adults it is important to develop messages that incorporate the terminology and use patterns used by at-risk populations in order to be salient and have the best chance of affecting behavior change. In designing the proposed data collection activities, we took several steps to ensure that this effort does not duplicate ongoing efforts and that no existing data sets would address the proposed study questions. We carefully reviewed existing data sets to determine whether any of them are sufficiently similar or could be modified to address FDA's need for information on blunt use and perceptions. Data sources we examined for this purpose include ongoing national surveillance systems such as the National Youth Tobacco Survey (NYTS), the Youth Risk Behavior Surveillance System (YRBSS), the National Health Interview Survey (NHIS), and the Population Assessment of Tobacco and Health (PATH). We concluded that these data sources do not include the necessary measures (e.g., use and susceptibility to blunts and/or blunt related knowledge, attitudes and beliefs and behaviors) nor sufficient sample sizes of Black/African American youth and young adults needed to fully understand product use and perceptions, as well as to explore subgroup differences among this audience most at risk of use.

5. Impact on Small Businesses or Other Small Entities

Respondents in this study will be members of the general public, specific subpopulations or specific professions, not business entities. No impact on small businesses or other small entities is anticipated.

6. Consequence of Collecting the Information Less Frequently

Respondents to this data collection will answer only once to ensure the participant burden is as low as possible. Without the data collection requested for this study, it would be difficult to understand LCC and blunt use and perceptions needed to develop public education programs that resonate with those most at risk for tobacco-related death and disease. Failure to collect these data could reduce effectiveness of the FDA's messaging, and therefore reduce the benefit of the messages for youth/young adults in the United States.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information that require the data collection to be conducted in a manner inconsistent with 5 CFR 1320.5(d)(2). The message testing activities fully comply with the guidelines in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

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

Emily Sanders
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-4269, Cell: 240-485-9209
E-mail: emily.sanders@fda.hhs.gov

Morgane Bennett
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-9281
E-mail: Morgane.Bennett@fda.hhs.gov

FDA collaborates with other federal government agencies that sponsor or endorse health communication projects, such as the Centers for Disease Control and Prevention, Office on Smoking and Health (CDC/OSH), the Substance Abuse and Mental Health Services Administration (SAMHSA) and the National Institutes of Health National Cancer Institute (NIH/NCI). These affiliations serve as information channels, help prevent redundancy, and promote use of consistent measures of effectiveness. Coordination activities include:

- Review of questionnaires for testing purposes;
- Sharing data; and
- Standardizing survey tools where at all possible.

The following individuals outside of the agency have been consulted on questionnaire development.

Nathaniel Taylor
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-316-3523
Email: ntaylor@rti.org

Jane Allen
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-597-5115
E-mail: Janeallen@rti.org

Amy Henes
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-541-7293
E-mail: ahenes@rti.org

Laurel Curry
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 202-728-2086
E-mail: lcurry@rti.org

9. Explanation of Any Payment or Gift to Respondents

As a token of appreciation, participants recruited through social media who complete and submit the full survey will receive a \$5 token of appreciation. Participants will be eligible to take the survey one time. There is no token of appreciation for completing the web screener. Participants will be informed that they will receive their token of appreciation within 5-7 business days of completing the survey.

This token of appreciation is warranted as we aim to over-recruit harder-to-reach populations, including people who are Black/African American and participants of lower socioeconomic status (SES). These populations are more likely to be cigarillo and blunt users (the target audience for our research), therefore it is essential that we can successfully recruit these populations to meet the goals of this study. The above populations are considered harder-to-reach for several reasons: (1) Historical and ongoing experiences with the health care system have caused mistrust among African Americans.¹ This continues to reduce our ability to recruit African American participants into all types of research studies. (2) Socially disadvantaged groups, including low SES, are consistently underrepresented in all types of research studies.² One reason for this may be because people who are lower SES may be unable to take time off work for research study participation. The token of appreciation treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate.³ When applied in a reasonable manner, tokens of appreciation are not an unjust inducement—they are an approach that acknowledges participants for their participation.⁴

In general, empirical studies show that incentives can increase response rates in cross-sectional surveys and reduce attrition in longitudinal surveys within some respondent populations.⁵

¹ Scharff DP, Mathews KJ, Jackson P, Hoffsuemmer J, Martin E, Edwards D. More than Tuskegee: Understanding Mistrust About Research Participation. *Journal of health care for the poor and underserved*. 2010; 21(3):879-897.

² Bonevski, B., Randell, M., Paul, C. et al. Reaching the hard-to-reach: a systematic review of strategies for improving health and medical research with socially disadvantaged groups. *BMC Med Res Methodol* 14, 42 (2014). <https://doi.org/10.1186/1471-2288-14-42>

³ Gelinas L, Largent EA, Cohen IG, Kornetsky S, Bierer BE, Fernandez Lynch H. A Framework for Ethical Payment to Research Participants. *N Engl J Med*. 2018;378(8):766-771. doi:10.1056/NEJMs1710591

⁴ Halpern, SD., Karlawish, JH., Casarett, D., Berlin, JA., Asch, DA. Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. *Archives of Internal Medicine*. 2004; 164(7), 801-803.

⁵ Singer E & Ye C. (2013). The use and effects of incentives in surveys. *The Annals of the American Academy of Political and Social Science*. 645(1), 112-141; LeClere F et al. (2012). Household early bird incentives: leveraging family influence to improve household response

Although the vast majority of published research on this topic is based on mail, telephone, or in-person surveys, there are now several studies on the effects of incentives within the context of a web-based survey. For example, a 2006 meta-analysis of 32 studies indicates that incentives increase the odds that potential respondents will begin a web survey, and a second meta-analysis of 26 studies shows that incentives increase the odds of completing a web survey once respondents have begun it.⁶

10. Assurance of Confidentiality Provided to Respondents

Generic 0910-0810 is covered underneath an approved umbrella PIA.

PII Collection

As part of this study, RTI, the contractor acting on behalf of FDA, is collecting and maintaining personally identifiable information (PII) about participants who complete the online screener and the online survey. The only PII we will be collecting is email address, IP address, and birthdate, but this information will be stored separately from each other and from survey responses (except for 24 hours after download when the fraud detection procedures are completed). We are not collecting any Protected Health Information, defined as “Personally identifiable information that relates to a person's health, medical treatment or payment, and which was obtained from a "covered entity" (health care provider, health plan, or healthcare clearinghouse), as defined by HIPAA (Health Insurance Portability and Accountability Act) regulations.” Survey data will be kept separate from PII and/or stored on the Federal Information Processing Standards (FIPS) 199 except for the 24-hour period after download when the combined dataset is stored temporarily on the study share drive so that the fraud detection procedures can be conducted. FDA will not have access to any PII.

This study is funded by the FDA, a Department of Health and Human Services supported agency, and is covered by a Certificate of Confidentiality (CoC). Section 2012 of the 21st Century Cures Act includes significant amendments, to the previous statutory authority for such protections, to enhance privacy protections for individuals who are the subjects of federally funded research, under subsection 301(d) of the Public Health Service Act (42 U.S.C. 241). Specifically, the amended authority requires the FDA to issue a CoC to investigators or institutions engaged in research funded by the Federal government to protect the privacy of individuals who are subjects of this research. We will notify participants in the consent form of the protections that the Certificate provides.

rates. In American Statistical Association Joint Statistical Meetings, Section on Survey Research; Cantor D et al. (2003). Comparing promised and pre-paid incentives for an extended interview on a random digit dial survey. In Presentation for the Annual Meeting of the American Association for Public Opinion Research, Nashville, TN; Singer E. (2002). The use of incentives to reduce nonresponse in household surveys. In Survey Nonresponse, eds. Groves RM et al. 163-78. New York, NY: Wiley; Singer E et al. (1998). Does the payment of incentives create expectation effects? Public Opin Q. 62, 152-64.

⁶ Görnitz AS. (2006). Incentives in web studies: methodological issues and a review. Int J Internet Science. 1(1), 58-70.

Overview of Data Collection System

All information will be collected electronically through a self-administered survey instrument hosted in a secure, online, web-based data collection system. Up to 1,550 participants will be recruited via social media. All participants will be screened for eligibility prior to administration of the survey instrument. The screener is designed to not reveal specifically why a respondent is not eligible. All respondents, regardless of age, gender, race/ethnicity, tobacco use behavior, and residence will complete the full screener. Respondents must complete all screener questions to find out whether they can move on to the study survey. To recruit participants, RTI will place ads on social media platforms, such as Facebook and Instagram. As much as possible, these ads will target potentially eligible respondents who are thought to be age 15-24 and are blunt users or are susceptible to blunt use. Given the high prevalence of blunt use among African American/Black populations, the study design will include oversampling of youth and young adults who identify as African American or Black.

Each participant will give feedback on their blunt and tobacco use status, followed by a series of questions about their knowledge, attitudes, and behaviors in regard to specific tobacco products and marijuana, and complete the survey by answering basic demographic information. The participant will complete the survey at the time of his or her choosing. There is no website content directed at children younger than 13 years of age.

Overview of How Information will be Shared and for What Purposes

All data will be downloaded from Qualtrics (which requires a password) and stored in databases only on RTI's secure shared drive and/or FIPS 199, which are only accessible by study staff trained in human subjects. At the completion of data collection, the databases will be deleted from our Qualtrics account and remain only on RTI's secure shared drive and FIPS 199. No PII will be shared with FDA.

Overview of the Impact the Proposed Collection will have on the Respondent's Privacy

The following procedures will be used to ensure participant privacy before, during, and after fielding: (1) PII in the form of participants' email addresses and birthdate will be stored separately from screening-related data and survey data, and email addresses and birthdate will be deleted after survey completion; (2) datasets and reports will not contain any PII; and (3) respondents' information will not be tied to their individual responses and all analyses will be conducted in the aggregate (i.e., any data used in reporting will not be attributed to individual participants). All datasets and reports delivered to FDA will not include PII.

PII will be collected in the form of email addresses for the purposes of distributing the token of appreciation and birthdate to confirm age. No additional personal identifiers (e.g., full name, phone number, social security number) will be collected aside from basic demographic information (e.g., gender, age, race). Other than the participant's email address, no other social media profile identifiers will be collected through the social media recruitment. PII will be stored separately from any survey responses.

Overview of Voluntary Participation

Potential participants will be advised of the nature of the survey, the length of time it will require, and that participation is voluntary. Participants will be assured that they will incur no penalties if they wish not to respond to the data collection as a whole or to any specific questions. Participants will have the option to decline to respond to any item in the survey for any reason and may drop out of the survey at any time. These procedures conform to ethical practices for collecting data from human participants.

Overview of Data Security

E-mail addresses and birthdate will each be collected separately in the Qualtrics survey platform and stored in separate isolated surveys that will contain a RTI-assigned unique ID and email address or birthdate. IP address will be collected in the survey platform in an isolated survey that contains IP address, RTI-assigned unique ID, and screener responses. 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 birthdate will not be collected in the same file.

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

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, and results will only be presented in aggregate form.

11. Justification for Sensitive Questions

The majority of questions asked will not be of a sensitive nature. However, it will be necessary to ask some questions that may be considered to be of a sensitive nature in order to assess specific health behaviors such as tobacco product use and marijuana use. These questions are essential to the objectives of this data collection. Although we do not anticipate any risks from these health questions, some participants may perceive them to be sensitive. To address any concerns about inadvertent disclosure of sensitive information, participants will be fully informed of the applicable privacy safeguards. The informed consent will notify participants that these topics will be covered in the survey.

Collection of detailed demographic information, including race/ethnicity, sexual orientation, and gender identity are necessary in order to assess disparities in tobacco use and possible

differences in campaign impact across different populations. Decades of research has shown significant disparities in tobacco use by race/ethnicity (e.g., Harlow et al., 2019; Odani et al, 2018), 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 (0910-0753) and for RESPECT (0910-0808).

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.

This study includes a number of procedures and methodological characteristics that will minimize potential negative reactions to these types of questions, including the following:

- Participants will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer;
- Web surveys are entirely self-administered and maximize respondent privacy without the need to verbalize responses; and

- Participants will be provided with contact information for the Principal Investigator should they have any questions or concerns about the study.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

An estimated one-time reporting burden for this collection will be approximately 868 hours (Table 1). This includes the time burden associated with the screener (2.5 mins per response), youth assent (2.5 mins per response), young adult consent (2.5 mins per response), and survey (15 mins per response). We will obtain a final sample size of 1,550 participants (775 youth and 775 young adults). We will need to screen approximately 10,000 potential participants (5,000 youth and 5,000 young adults) to obtain our target sample size.

Table 1. Estimated Annual Reporting Burden

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response in hours	Total Hours
Screening						
Youth aged 15–17	Youth Recruiting and Screening	5,000	1	5,000	0.0416 (2.5 minutes)	208
Young Adult aged 18-24	Adult Recruiting and Screening	5,000	1	5,000	0.0416 (2.5 minutes)	208
Informed Consent						
Youth aged 15–17	Youth Assent	775	1	775	0.0416 (2.5 minutes)	32
Young Adult aged 18-24	Adult Consent	775	1	775	0.0416 (2.5 minutes)	32
Survey						
Youth aged 15–17	Online Survey	775	1	775	0.25 (15 minutes)	194
Young Adult aged 18-24	Online Survey	775	1	775	0.25 (15 minutes)	194
Total Annualized Hours						868

12b. Annualized Cost Burden Estimate

Respondents participate on a purely voluntary basis and, therefore, are subject to no direct costs other than time to participate. There are also no start-up or maintenance costs.

To calculate the estimate annual cost, the mean hourly wage of \$7.25 was used for youth and \$26.95 was used for young adults. The youth price represents the minimum wage, and the young adult costs represent the mean hourly wage for other occupation earnings from the U.S. Department of Labor Bureau of Labor Statistics (May 2020 data).

RTI has conducted many smoking-related surveys of similar length among youth and adults. We have examined diagnostic data from each of these prior surveys and estimate that data collection for this study will take, on average, 2.5 minutes per respondent for screening, 2.5 minutes per respondent for assenting/consenting, and approximately 15 minutes per respondent for the online surveys. Thus, assuming an average hourly wage of \$7.25 and \$26.95 (youth and

young adult, respectively), the estimated one-year annualized cost to participants will be \$14,843. The estimated value of respondents' time for participating in the information collection is summarized in Table 2.

Table 2. Estimated Annual Cost

Type of Respondent	Activity	Annual Burden Hours	Hourly Wage Rate	Total Cost ¹
Youth aged 15-17	Youth Recruiting and Screening	208	\$7.25	\$1,508
	Youth Assent	32	\$7.25	\$232
	Online Survey	194	\$7.25	\$1,407
Young Adult aged 18-24	Adult Recruiting and Screening	208	\$26.95	\$5,606
	Adult Consent	32	\$26.95	\$862
	Adult Survey	194	\$26.95	\$5,228
Total				\$14,843

¹ Cost was rounded up to the next dollar.

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital, start-up, operating, or maintenance costs associated with this data collection.

14. Annualized Cost to the Federal Government

This information collection is funded through a contract with RTI. The estimated costs attributable to this data collection are \$753,587 per year. (Table 3). There are additional contract-funded activities occurring before and after this data collection that include project planning and data analysis. Other activities outside this data collection include coordination with FDA, instrument development, reporting, Advarra IRB, project management and progress reporting.

Table 3. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total¹
GS-12	5%	\$86,335	\$4,317
GS-13	10%	\$102,663	\$10,266
GS-13	10%	\$102,663	\$10,266
		Total Annual Salary Costs	\$24,849
Annual Contract Cost			\$728,738
Total Annual Cost			\$753,587

¹ Cost was rounded up to the next dollar.

15. Explanation for Program Changes or Adjustments

This is a new individual generic data collection.

16. Plans for Reporting and Project Time Schedule

Data from this information collection will be used to enable the FDA to develop public education programming that resonate with those at risk for tobacco use and tobacco-related death and disease. Findings from these analyses will be used to inform FDA CTP health communication strategy and messaging aimed at youth and young adults in the U.S.

Reporting

At the end of the study, a draft report and a final report containing background information on the project objectives, scope and methodology, and key findings and conclusions will be completed. The approximate dates for completing project tasks are listed in Table 4.

Table 4. Approximate Project Schedule

Project Activity	Date
Survey	Begins following study approval and continues for approximately 10 weeks
Preparation of analytic data file	Approximately 1–2 weeks after completion of data collection
Data Analysis	Approximately 3–5 weeks after completion of data collection
Report Writing	Approximately 6-8 weeks after completion of data collection

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Not applicable. All data collection instruments will display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

These information collection activities involve no exception to the Certification for Paperwork Reduction Act Submissions.

References

- Antognoli, E., Koopman Gonzalez, S., Trapl, E., Cavallo, D., Lim, R., Lavanty, B., & Flocke, S. (2018). The social context of adolescent co-use of cigarillos and marijuana blunts. *Substance Use & Misuse*, 53(4), 654-661.
- Cohn A, Johnson A, Ehlke S, Villanti AC. Characterizing substance use and mental health profiles of cigar, blunt, and non-blunt marijuana users from the National Survey of Drug Use and Health. *Drug Alcohol Depend*. 2016 Mar 1;160:105-11.
- Dai, H., & Leventhal, A. (2019). Prevalence of e-cigarette use among adults in the United States, 2014-2018. *JAMA*. 322(18), 1824-1827.
- Gentzke, A. S.; Wang, T. W.; Jamal, A.; Park-Lee, E.; Ren, C.; Cullen, K. A.; Neff, L. Tobacco Product Use among Middle and High School Students. *MMWR Surveill Summ* 2020, 69 (50), 1881–1888.
- Giovenco, D. P., Spillane, T. E., Mauro, C. M., & Martins, S. S. (2018). Cigarillo sales in legalized marijuana markets in the US. *Drug and alcohol dependence*, 185, 347-350.
- Kasza, K., Ambrose, B., Conway, K., et al. (2017). Tobacco-product use by adults and youths in the United States in 2013 and 2014. *N. Engl J. Med*. 376(4), 342-353.
- Rolle, I. V., Kennedy, S. M., Agaku, I., Jones, S. E., Bunnell, R., Caraballo, R., ... & McAfee, T. (2015). Cigarette, cigar, and marijuana use among high school students—United States, 1997–2013. *Morbidity and Mortality Weekly Report*, 64(40), 1136-1141.
- Wang, T. W.; Gentzke, A. S.; Creamer, M. R. Tobacco Product Use and Associated Factors among Middle and High School Students. *MMWR Surveill Summ* 2019, 68 (SS-12), 1–22.
- Wang, X., Kim, Y., Borowiecki, M., Tynan, M. A., Emery, S., & King, B. A. (2021). Trends in Cigar Sales and Prices, by Product and Flavor Type--United States, 2016-2020. *Nicotine and Tobacco Research*, Nov. <https://doi.org/10.1093/ntr/ntab23>