

**U.S. Food and Drug Administration
Center for Tobacco Products
The Real Cost Campaign: Media Tracking Study
OMB No. 0910-0810
Supporting Statement A: Summary**

- The goal of this study is to monitor awareness and receptivity of CTP’s public education efforts, as well monitor and validate changing knowledge, attitudes, beliefs, and behaviors related to tobacco use in youth. The research will also obtain input to optimize advertising concepts designed to prevent tobacco use. The research will be conducted with youth aged 13 to 17 who either: 1) are at risk of initiating use of tobacco products, or 2) have experimented with tobacco products.
- Online surveys will be conducted with youth in the United States recruited via KDH Research & Communication and FCB’s contractor, Marketing Workshop, through online sources to monitor perceptions about tobacco products. Once approvals are received, we will begin data collection for a national, online self-administered survey of up to 750 youth (ages 13-17) approximately quarterly for six months. The survey will be repeated with a new cross-sectional sample, with up to 2 rounds of data collection. Each sample will be freshly recruited.
- The results of the surveys will be used to inform specified recommendations around the U.S. Food and Drug Administration Center for Tobacco Products’ (CTP) public education programs’ impact and effectiveness in reducing tobacco-related death and disease.
- Results of the survey will help CTP better understand:
 - Awareness and receptivity of CTP’s public education video advertisements while in market
 - Reactions to proposed messages for public education campaigns related to tobacco products among youth ages 13 to 17 years in the United States.
 - Knowledge, attitudes, beliefs, and behaviors in relation to tobacco use in youth.
 - Personality characteristics, interests, and lifestyle characteristics of CTP’s public education target audience.
- **REQUESTED APPROVAL DATE: 07/21/2022**

Study Materials (attached):

- Appendix A. Email Invitation for Parents of Youth
- Appendix B. Parental Notification and Opt-Out Information
- Appendix C. Youth Assent
- Appendix D. Screener
- Appendix E. Survey

**U.S. Food and Drug Administration
Center for Tobacco Products
The Real Cost Campaign: Media Tracking Study
OMB No. 0910-0810 Supporting Statement Part A**

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

In support of the U.S. Food and Drug Administration’s (FDA) efforts to refresh campaign messaging, the Center for Tobacco Products (CTP) will conduct a quantitative study to inform the development of appropriate messaging for FDA’s The Real Cost campaign. In 2019, about 6.2 million U.S. middle and high school students were current users of some type of tobacco product (Wang, Gentzke & Creamer, 2019). Specifically, 5.8% high school students used cigarettes and 27.5% used e-cigarettes and 13.3% of middle and high school students used both cigarettes and e-cigarettes (Wang, Gentzke & Creamer, 2019). Young people continue to represent a priority population when it comes to prevention messaging. 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 (CDC, 2014 https://www.cdc.gov/tobacco/stateandcommunity/best_practices/index.htm)

In an effort to continuously improve FDA’s public education programs’ impact and effectiveness in reducing tobacco-related death and disease in an ever-evolving media and tobacco product landscape, this Media Tracking study will collect primary data to track advertisement and educational message performance and better understand CTP’s public education program’s target audience.

Starting in Q1 of 2021, this study was fielded once per quarter with a cross-sectional sampling approach using an online survey. This ICR is a continuation of the previously approved study. We are seeking approval for another 6 months of data collection.

The study will be conducted using self-administered online surveys on personal computers or web-enabled mobile devices. The study will use an online survey of up to 2,000 youth ages 13 to 17 years for six months. Each participant will spend approximately 21 minutes to complete the study (2-minute screener, 2-minute assent, 17-minute survey). This survey will ask participants to provide awareness of video advertisements in market, feedback on tobacco product use, knowledge, attitudes, and beliefs, media use habits, and reactions to advertisement concepts or ideas.

2. Purpose and Use of the Information

Online surveys will be conducted with youth recruited via KDH Research & Communication and FCB's contractor, Marketing Workshop, through online sources to monitor perceptions about tobacco products. As soon as approvals are received, we will begin data collection for a national, online self-administered survey of up to 750 youth (ages 13-17) approximately quarterly (and up to 2 times) for six months. The survey will be repeated with a new cross-sectional sample. Each sample will be freshly recruited, but respondents will be eligible to participate again six months after initial participation.

The results of this survey will be used to inform specific recommendations around FDA's public education programs' impact and effectiveness in reducing tobacco-related death and disease.

The study aims to explore the following questions:

- What are the reactions to currently available tobacco prevention advertisements related to tobacco products among youth ages 13 to 17 years in the United States? How are the ads performing in market?
- What are the reactions to proposed messages for media campaigns related to tobacco products among youth ages 13 to 17 years in the United States?
- What are the trends in demographics and psychographics among youth ages 13 to 17 years in the United States who use tobacco products?
- What are the trends in media habits among youth ages 13 to 17 years in the United States?
- What are the trajectories in tobacco related knowledge, attitudes, beliefs, and behaviors among youth ages 13 to 17 years in the United States across multiple time points?

3. Use of Information Technology and Burden Reduction

This study will rely on online survey data collection to collect primary data. 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 an online survey will allow for more participants to respond in a cost-effective and timely manner. The self-administered, online survey makes data processing and analysis quicker, 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., tobacco use) less threatening and enhances response validity and response rates. Only KDH Research &

Communication and Marketing Workshop will ever have data with PII. FCB and FDA will not have access to PII.

4. Efforts to Identify Duplication and Use of Similar Information

The world of youth changes quickly, and ongoing data collection will help us understand ad performance in market “in real time”. The types of tobacco products on the market change quickly, and it is important for advertising to reflect the current state of tobacco use to be salient and have the best chance of affecting change in tobacco use. 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 already 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 this information. 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 also reviewed data collected to evaluate other national tobacco-focused media campaigns such as CDC’s Tips from Former Smokers and FDA’s The Real Cost, as well as other CTP surveillance mechanisms. We concluded that these data sources do not include the measures, nor do they collect data frequently enough to assess in-market metrics of video advertisement performance, as well as rapidly changing knowledge, attitudes, and beliefs around tobacco products and media use habits.

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 in a six-month period to ensure the participant burden is as low as possible. Without the data collection requested for this study, it would be difficult to optimize FDA’s public education advertising and to identify trends knowledge, attitude, and beliefs around tobacco products, as well as trends in media use. While each iteration of the data collection may be similar from time point to time point, the goal is to identify these trends over time and their changes. Failure to collect these data could reduce effectiveness of the FDA’s messaging, and therefore reduce the benefit of the messages for youth 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:

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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 proposed messages for advertisements;
- Review of surveys for testing purposes;
- Sharing data; and
- Standardizing survey tools where at all possible.

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

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9. Explanation of Any Payment or Gift to Respondents

As a token of appreciation, participants recruited who complete and submit the survey will receive a Visa gift card worth \$5. Such tokens are commonly used by research agencies to recruit participants efficiently and effectively; parents/guardians or individual members who choose to be a part of these online panels as a thank you for their time. We estimate that the survey will take about 17 minutes to complete, with the entire study taking 21 minutes (including the 2-minute screener and 2-minute assent process). The token of appreciation amount not only reflects the burden of time to participate, it will also ensure that the respondent pool is recruited within a tight timeframe, encourage participant cooperation, and convey appreciation for contributing to this study.

The use of a modest token is expected to enhance survey response rates without biasing responses. A smaller compensation amount would not appear sufficiently attractive to participants and result in slower recruitment. Our pool of respondents in the target audience is limited to a subset of youth who are using or are susceptible to using tobacco products. Some products, such as cigarettes or cigar products, have low rates of use among youth, making users a potentially hard to reach population. The use of an incentive will help us recruit this population in a timely manner. At-risk youth, such as those who use tobacco products or who are susceptible to using tobacco, can be hard to reach for survey research, but the use of a token of appreciation can be an effective means of recruiting and retaining participants from these populations

Because some participants in this study may use tobacco, it is expected that the token of appreciation will help us recruit and retain this at-risk population into our research, increasing the likelihood we will have a diverse sample (Booker et al., 2011; Caldwell et al., 2010).

Having a token of appreciation as a \$5 Visa gift card ensures that all participants are treated equally, which reflects our human subjects' commitment to equity in research participation and a fair distribution of burden and benefit across participants.

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

- The Media Tracking study (OMB Control Number 0910-0810) was approved in 2021 with a \$5 token of appreciation.
- The CTP Monthly Monitoring Study (OMB Control Number 0910-0810) was approved with a \$5 token of appreciation for a survey of similar length 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.

Overall, tokens of appreciation are important for both data quality and project management. An empirical test of the power of tokens of appreciations found that cash incentives increased response rates by 30% and providing the incentive up front increased response rates by 50% (Young et al., 2015).

10. Assurance of Confidentiality Provided to Respondents

OMB Control Number 0910-0810 is covered underneath a Privacy Impact Assessment that has been approved by the Department of Health and Human Services (PIA Unique Identifier: P-9008729-198376).

PII Collection

As part of this study, KDH Research & Communication and FCB's contractor, Marketing Workshop, is collecting and maintaining personally identifiable information (PII) about participants who complete the online screener and the online surveys. The only PII that will be collected is email address, IP address, and zip code, but this information will be stored separately from each other and from survey responses. 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 always be kept separate from PII. Only KDH Research & Communication and Marketing Workshop will ever have data with PII. FDA will not have access to 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 assent form of the protections that the Certificate provides.

Overview of Data Collection System

All information will be collected electronically through a self-administered survey instrument hosted in a secure, online data collection system. Approximately 2,000 participants will be

recruited via online panel over the course of six months. The online panel provider may use social media platforms to recruit additional participants as needed to augment their existing panels.

Step One: Screener

To recruit for the survey, KDH Research & Communication and FCB's contractor, Marketing Workshop will contact existing panelists to gauge interest in and eligibility for study participation. We will screen respondents for eligibility through their age and tobacco use behavior (i.e., susceptible to, or experimenters of, tobacco products). All participants will be screened for eligibility prior to administration of the survey instrument. The screener does not reveal specifically why a respondent is eligible or ineligible for further participation. 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 media tracking survey.

Step Two: Survey

Each participant that meets eligibility criteria will move directly into the survey. In the survey, participants will report awareness of current advertising, watch a campaign ad currently on air and give answers to a series of questions about their knowledge, attitudes, and behaviors regarding specific tobacco products. They will also answer basic demographic information and provide media use behavior. 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 Confirmit, the online data collection platform (which requires a password) and stored in databases only on Marketing Workshop's secure shared drive and which are only accessible by study staff trained in human subjects. At the completion of data collection, the databases will be deleted from the Confirmit account and remain only on Marketing Workshop's secure servers for a period of three years.

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, zip codes, and IP addresses will be stored separately from screening-related data and survey data; (2) email addresses, zip codes, and IP addresses will be deleted after survey completion; (3) datasets and reports will not contain any PII; and (4) 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, FCB (FDA Contractor) and KDH Research & Communication (FDA sub-contractor) will not include PII.

PII will be collected in the form of email addresses for the purposes of data quality assurance. Zip codes will be collected to verify that participants are within determined geographic targets for the study and for geographic diversity. IP Address will be collected automatically to reduce fraudulent activity and verify participant country of origin. 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, and race). 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

All participants will be asked to provide their email address, and IP address will be collected automatically. (1) Email addresses will be checked against all current respondent data to avoid duplicates and reduce fraudulent activity. If multiple emails have the same IP address, researchers will review the data, retain the first recorded response, and remove duplicates from the final analytical dataset. (2) Participants' email addresses will also be collected when providing assent to participate in the study to send participants a record of the completed assent forms. (3) Researchers may also contact participants in the unlikely case that there is a breach of confidentiality, for example, as a result of hacking or an issue with delivery of the token of appreciation.

Confermit is a trusted survey tool used by both researchers and marketing companies alike. Confermit is provided as an online application, accessed using a modern Internet browser where data are stored in a single secure data center. The database servers that store respondent and response data are placed behind two tiers of firewalls, and data can only be accessed through the Confermit applications. No application users have direct database access, the servers are only accessible for database administrators. Remote server access is only available to system administrators through network controls and secure VPN tunnels. If outside the corporate network, dual factor authentication is required to establish a secure VPN tunnel into the corporate network (in order to access the production VPN through a hop-server), and only computers that are under Confermit's control are allowed to connect to the VPN. Confermit surveys do not require any user-identifiable information to be transmitted between page submissions. Surveys use a combination of hidden form fields and system generated identifiers to identify the respondent. Survey pages include meta code to prevent them from being cached on the client. No information is stored on a respondent's computer when the browser is closed. To further prevent caching, all surveys are available over HTTPS. Data will be stored on dedicated servers with a redundant multi-tier network security infrastructure.

Only KDH Research & Communication and Marketing Workshop will ever have data with PII. FCB and FDA will not have access to PII. All PII except for informed assents will be destroyed no later than three months after the last survey is completed. Assents will be destroyed in three years. The data are backed up on a daily basis. No one can access the data unless it is required by law to protect participant rights or to comply with judicial proceedings, a court order, or other legal process. Data will be maintained on secure servers for a period of three years and then destroyed securely using best practices.

Any online panel used in this study will follow the Standard of Good Practice (SoGP, <https://www.securityforum.org/research/thestandardofgoodpractice2016/>) security practices which emphasize security management, safe business application protocol, safe computer installations, network fidelity, awareness of systems development requirements, and safety of the end-user environment. Following these guidelines, the monitoring of data and sensitive information will take place following the SoGP security practices such as limiting access to information and data encryption. FCB and FDA will receive de-identified data transmitted through an encrypted format via an encrypted and secure broadband connection.

When the raw data are downloaded from Conconfirm, the data will be in two datasets paired by participant (1) screener responses, and (2) survey responses. The respective screener and survey datasets will be merged into a participant data set using unique identifiers that do not contain PII. KDH Research and Communication and Marketing Workshop will clean the data using SPSS. The datasets will go through a thorough review and data cleaning process to remove unfinished, duplicate, and/or fraudulent surveys, and a de-identified dataset will be created for analysis. Only members of the research team (i.e., FDA CTP, KDH Research and Communication, and FCB) will have access to the de-identified raw data files. FDA/CTP and FCB will never receive any PII.

11. Justification for Sensitive Questions

The majority of questions asked will not be sensitive, but some will ask about specific health behaviors such as tobacco product use. These sensitive 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. Questions about messages concerning lifestyle (e.g., tobacco product use) and some demographic information, such as race and ethnicity could also be considered sensitive, but not highly sensitive. To address any concerns about inadvertent disclosure of sensitive information, participants will be fully informed of the applicable privacy safeguards. The informed assent protocol will notify participants that these topics will be covered in the survey. 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.
- Online surveys are entirely self-administered and maximize respondent privacy without the need to verbalize responses; and
- Participants will be provided with a phone number and email address 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 2,100 hours (Table 1). We will obtain a final sample size of 2,000 youth (13- 17). We will survey up to 750 youth approximately quarterly for up to two rounds of data collection.

Table 1. Estimated Annual Reporting Burden

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response	Total Hours ¹
Parent Email Invitation/Opt-Out						
Parents of youth aged 13–17	Youth Recruiting	5,000	1	5,000	3 minutes	250
Screening						
Youth aged 13–17	Youth Recruiting and Screening	5,000	1	5,000	2 minutes	167
Informed Assent						
Youth aged 13–17	Youth Assent	2,000	1	2,000	2 minutes	67
Survey						
Youth aged 13–17	Online Survey	2,000	1	2,000	17 minutes	567
Total Annualized Hours						1,051

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. Marketing Workshop has conducted many smoking-related surveys of similar length among youth and adults. We have examined diagnostic data from prior surveys and estimate that data collection for this study will take approximately 3 minutes for recruiting, 2 minutes per respondent for screening, 2 minutes per respondent for assenting, and approximately 17 minutes per respondent for the online surveys.

To calculate the estimate annual cost, the mean hourly wage of \$7.25 was used for youth. The youth price represents the minimum wage represent the mean hourly wage for other occupation earnings from the U.S. Department of Labor Bureau of Labor Statistics (May 2020 data). There are no direct costs to respondents associated with participation in this information collection. Marketing Workshop has conducted many smoking-related surveys of similar length among youth and adults. Thus, assuming an average hourly wage of \$7.25 for youth and \$28.43 for parents of youth, the estimated one-year annualized cost to participants will be \$12,915. 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
Parents of youth aged 13-17	Youth Recruiting	250	\$28.43	\$7,108
Youth aged 13-17	Youth Recruiting and Screening	167	\$7.25	\$1,211
	Youth Assent	67	\$7.25	\$486
	Online Survey	567	\$7.25	\$4,111
Total				\$12,915

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 FCB New York. 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, KDH Research and Communication IRB, project management and progress reporting. This information collection will occur for six months..

Table 3. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total ¹
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

Year one of this study was previously approved under ICR reference # 202101-0910-013. We are submitting this new ICR for another six months of data collection. The methodology is identical to the previous ICR, but the sampling frame is changed. Young adults have been removed from the sampling plan and the eligibility criteria has changed to all tobacco products use, not just vaping.

16. Plans for Reporting and Project Time Schedule

Data from this information collection will enable the FDA to monitor and assess awareness and receptivity to CTP’s public education campaign advertisements, as well as knowledge, attitudes, and beliefs around tobacco products and trends in media use behavior. This activity will allow the FDA to set priorities and raise situational awareness because tobacco use is a threat to public health. These data will allow us to examine ad performance to optimize it, and track and determine trends in tobacco product and media platform choices so that the FDA can develop new media campaign messages related to tobacco products that resonate with and effectively reach youth ages 13 to 17 years old in the United States. Findings from these analyses will be used to inform FDA CTP health communication strategy and messaging.

Reporting

Reporting will consist of quarterly summaries of key results and findings. At the end of the study, 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	August 2022 to January 2023(Approximate, pending OMB approval)
Data Analysis	Approximately 1–2 weeks after completion of data collection
Report Writing	Approximately 2-4 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

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- U.S. Department of Health and Human Services. Let's Make the Next Generation Tobacco-Free: Your Guide to the 50th Anniversary Surgeon General's Report on Smoking and Health. Published online July 2015. <https://www.hhs.gov/sites/default/files/consequences-smoking-consumer-guide.pdf>
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- Young, J. M., O'Halloran, A., McAulay, C., Pirodda, M., Forsdike, K., Stacey, I., & Currow, D. (2015) Unconditional and conditional incentives differentially improved general practitioners' participation in an online survey: randomized controlled trial. *Journal of Clinical Epidemiology*, 68(6), 693-697.