

Food and Drug Administration
Evaluation of the Food and Drug Administration’s General Market Youth Tobacco Prevention
Campaigns

OMB Control Number 0910-0753-Extension

SUPPORTING STATEMENT PART A

A. Justification

1. Circumstances Making the Collection of Information Necessary

On June 22, 2009, the Food and Drug Administration (FDA) was granted new authority to regulate the manufacture, marketing, and distribution of tobacco products and educate the public about the dangers of tobacco use. Under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (P.L. 111-31), FDA is responsible for protecting the public health and reducing tobacco use among minors. Section 1003(d)(2) (D) of the Food, Drug and Cosmetic Act (21 U.S.C. Section 393(d)(2)(D)) and Sections 2, 3, 105, 201, 204, 904, and 908 of the Tobacco Control Act support the development and implementation of FDA public education campaigns related to tobacco use. Since 2009, FDA has regulated cigarettes, smokeless, and roll-your-own tobacco. In 2016, FDA began regulating all forms of tobacco, including cigars, hookah and pipe tobacco, and e-cigarettes. Accordingly, FDA is implementing multi-strategy youth-targeted public education campaigns to reduce the public health burden of tobacco use that includes general market paid media campaigns, geo-targeted campaigns to reach specific target audiences, community outreach activities, and a comprehensive social media effort.

Tobacco use is the leading preventable cause of disease, disability, and death in the United States. More than 440,000 deaths are caused by tobacco use each year in the United States (USDHHS, 2010). Each day, more than 3,600 youth in the United States try their first cigarette, and an estimated 900 youth become daily smokers (NSDUH, 2011). The FDA Center for Tobacco Products (CTP) was created to carry out the authorities granted under the 2009 Tobacco Control Act to educate the public about the dangers of tobacco use and serve as a public health resource for tobacco and health information. In 2014, prevalence of e-cigarette use (also called vaping) surpassed that of cigarettes among youth in high school. By 2018, the FDA considered the increase in e-cigarette use an “epidemic.” Thus, in 2018, FDA added e-cigarettes as an important focus of FDA’s youth-targeted public education campaigns.

Through CTP, FDA researches, develops, and distributes information about tobacco and health to the public, professionals, various branches of government, and other interested groups nationwide using a wide array of formats and media channels. CTP collaborates closely with the Centers for Disease Control and Prevention’s Office on Smoking and Health, which has experience implementing and evaluating national anti-tobacco media campaigns. FDA is currently implementing evidence-based youth tobacco prevention campaigns, relying on paid media advertising that highlights the negative health

consequences of tobacco use. The objective of this evaluation is to measure the effectiveness of CTP public education campaigns designed to reduce tobacco use among youth ages 11 to 18. FDA's general market youth prevention campaigns focus on reducing tobacco use in the following audience segments: (1) youth who have not tried FDA-regulated tobacco products (non-tryers), (2) youth who are intermittent users of FDA-regulated tobacco products (experimenters), and (3) youth in rural areas who are susceptible to or use smokeless tobacco products. The goal of the information collection is to evaluate the effectiveness of these efforts in affecting specific cognitive and behavioral outcomes related to tobacco use that are targeted by the campaigns.

Several components of this evaluation are complete. We have concluded evaluation of the Rural Male Youth Smokeless campaign targeted to boys in rural areas susceptible to or using smokeless tobacco products. We have also concluded the Media Tracking Survey, which complemented the general market campaign evaluations. We have concluded evaluation of the General Market Youth Tobacco Prevention campaign for Cohort 1 and have also completed the baseline and first follow-up surveys for the Cohort 2 evaluation. This supporting statement describes components of the Cohort 2 evaluation that remain to be completed – follow-up 2 and follow-up 3.

The evaluation is designed to measure awareness of and exposure to FDA's youth tobacco prevention campaigns among youth in targeted areas of the U.S. and to assess their impact on outcome variables of interest. The evaluation relies on in-person data collection and web-based surveys self-administered on personal computers. Baseline data collection for the General Market Youth Tobacco Prevention campaign evaluation (Cohort 2) consists of an in-person survey of youth and their parent/guardian. Youth in the study are also invited to complete follow-up surveys at 8-month intervals following baseline data collection. The follow-up surveys are conducted largely in person (70%), with the remainder (30%) conducted via a web-based survey. The baseline and follow-up surveys include youth awareness of and exposure to the public health campaigns and measures of tobacco-related beliefs, attitudes, intentions, and behaviors. These survey instruments have been previously approved by OMB and are included in Attachment 2_E2c.

The longitudinal evaluation design allows us to calculate baseline-to-follow-up changes in campaign-targeted outcomes and facilitates analysis of relationships between individuals' exposure to the campaigns and pre-post changes in tobacco-related beliefs and behaviors. We hypothesize that if the campaigns are effective, the baseline-to-follow-up changes in outcomes should be larger among individuals exposed to the campaigns more frequently (i.e., dose-response effects). Eligible youth are aged 11 to 16 at baseline and 13 to 19 by the end of data collection, allowing us to follow the same youth over time and understand tobacco initiation, prevalence, and cessation for the campaigns' target audience of youth aged 12 to 17.

The requested data collection is an evaluation designed to closely assess the planned media dose of FDA campaign advertisements across the U.S. The evaluation relies on a pre-post evaluation design that leverages natural and created variation in exposure to

campaign messages across media markets. As such, the highest standard of evidence for causal relationships between health marketing campaigns and behavior change is the demonstration of changes in behavioral outcomes of interest by media dose (e.g., Farrelly et al., 2005, 2009, 2012). The effect of the campaigns on tobacco-related outcomes will be examined using two types of campaign exposure measures, market-level media dose and self-reported campaign exposure at the individual level.

Exogenous market-level doses of media will be measured with advertising targeted rating points (TRPs). TRPs are based on Nielsen ratings for the television programs or other media platforms on which campaign ads air. The primary hypothesis of this approach is that individuals who reside in media markets that receive higher doses of campaign media will exhibit an increased likelihood of behavior change, such as decreased intentions to use tobacco. This hypothesis is testable with the use of market-level campaign TRP data in combination with individual-level survey data on outcomes of interest and generally requires two conditions be met: (1) reasonable randomness in the media delivery at the market level and (2) sufficient variation in TRPs to identify statistical relationships between individual-level survey data and market-level TRPs. However, campaign media are not delivered in random doses across U.S. media markets. This non-randomness in media delivery can potentially obscure campaign effects or lead to spurious effects if the media delivery is based on market characteristics that are also correlated with outcomes of interest, such as smoking susceptibility. Moreover, the use of TRPs for determining the impact of a campaign can be hindered by a lack of market-to-market variation in media dose. While variation may increase as campaign ads are aired across the U.S. over time, we do not know a priori whether enough variation in media delivery across markets exists and can be used to test hypotheses based on TRPs.

A second measure of campaign exposure, self-reported exposure, will also be used to examine campaign effects given the limitations of market-level exposure measures. The primary hypothesis of this approach is that individuals who self-report greater frequency of exposure to campaign advertisements will exhibit an increased likelihood of behavior change. This approach may result in greater overall variation in exposure and potentially increased statistical power to identify associations between campaign advertisements and key outcomes of interest. The primary limitation of this approach is that self-reported measures of exposure are subject to “selective attention” bias whereby smokers who are more willing to quit can also be more attentive to campaign messages and thus more likely to indicate exposure. Because this can obscure the direction of causality for campaign effects, we will account statistically for preexisting selective attention. In summary, the specific and frequent measurement of both market-level and individual-level campaign exposure requested as part of this data collection effort are necessary to accurately evaluate campaign exposure and potential impact while mitigating the limitations of one approach in isolation.

2. Purpose and Use of the Information Collection

The information obtained from this data collection will be used to inform FDA, policy makers in the United States, prevention practitioners, and researchers about the extent of youth's exposure to the campaigns' messages and the extent to which exposure to these messages is associated with changes in target outcomes. While not exhaustive, the list below illustrates a range of purposes and uses for the information collection:

- Provide critical data on the reach of the campaigns among youth in the United States, particularly with estimates of the proportion of the population that was exposed to the campaigns.
- Understand the influence of the campaigns on beliefs, attitudes, intentions, and behaviors around tobacco use.
- Inform FDA, policy makers, and other stakeholders on the impact of the campaigns overall.
- Inform the public about the impact of the campaigns.
- Inform future programs that may be designed for similar purposes.

To achieve these goals, data collection consists of a baseline interview and three follow-up interviews with selected parents and youth. The in-person baseline household data collection for parents and youth occurs over a 3-month period, with most data collection occurring in the first two months. Longitudinal follow-up surveys occur in 8-month intervals following the baseline data collection. The follow-up surveys are conducted largely in person (approximately 70%), with the remainder conducted via a web-based survey (approximately 30%). Eligible youth are aged 11 to 16 at baseline and 13 to 19 by the end of data collection. This design allows the same youth to be followed over time and provides the data needed to address the study's goals.

Below we provide an overview of the status of data collection since approval of the initial OMB package in October 2013 and OMB extension approved in September 2016.

Evaluation of the General Market Youth Tobacco Prevention Campaign

As noted above, the Cohort 1 study, consisting of a baseline and three follow-up surveys, is concluded. We have also completed the baseline and first follow-up data collection for Cohort 2. Information has been collected about youth awareness of and exposure to campaign advertisements and youth knowledge, attitudes, and beliefs related to tobacco use. In addition, the surveys have measured tobacco use susceptibility and current use. Information has been collected on demographic variables including age, sex, race/ethnicity, grade level, and primary language. The Cohort 1 study is now complete; the Cohort 2 study is ongoing.

Evaluation of the Rural Male Youth Smokeless Tobacco Campaign

Baseline data collection for the rural male youth smokeless component of the evaluation study began in January 2016 and the final follow up was completed in December 2018. The Rural Male Youth Smokeless Campaign component of the evaluation differs from the General Market Campaign component in that only males in the age range are considered eligible. This study is now complete.

Media Tracking Survey

The media tracking survey consists of assessments of youth aged 13 to 17 that have been conducted periodically during the campaign period. The tracking survey assesses awareness of the campaign and receptivity to campaign messages. These data provide critical evaluation feedback to the campaigns and are conducted with sufficient frequency to match the cyclical patterns of media advertising and variation in exposure to allow for mid-campaign refinements. This study is now complete.

3. Use of Improved Information Technology and Burden Reduction

This evaluation relies on in-person surveys for baseline data collection and in-person and Web surveys for follow-up waves. The proposed approach of in-person recruitment and online surveys provides a number of methodological advantages, including increased accuracy in measurement of key variables of interest, sample characteristics that are representative of the population of interest, and reduced burden on study participants. This methodology permits the instrument designer to incorporate into the questionnaire routings that might be overly complex or not possible with alternative methods. The laptop computer used to collect youth data can be programmed to implement complex skip patterns and fill specific wordings based on the respondent's previous answers. Interviewer and respondent errors caused by faulty implementation of skip instructions are virtually eliminated. Second, this methodology increases the consistency of the data. The computer can be programmed to identify inconsistent responses and attempt to resolve them through respondent prompts. This approach reduces the need for most manual and machine editing, thus saving time and money. In addition, it is likely that respondent-resolved inconsistencies will result in data that are more accurate than when inconsistencies are resolved using editing rules. FDA estimates that 100% of the respondents will use electronic means (i.e., laptop computer, tablet) to complete the evaluation surveys.

The self-administered technology for the survey permits greater expediency with respect to data processing and analysis (e.g., a number of back-end processing steps, including coding and data entry). Data are transmitted electronically at the end of the day, 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. Finally, as noted above, this technology permits respondents to complete the interview in privacy. Providing the respondent with a methodology that improves privacy makes reporting of potentially embarrassing or stigmatizing behaviors (e.g., tobacco use) less threatening and enhances response validity and response rates.

Interviewers use hand-held tablets to conduct household screenings and baseline surveys with parents. The primary advantage of this computer-assisted methodology is improved accuracy in selecting the correct household member for an interview. The computer automatically selects the correct household member based on the demographic variables entered, thus substantially reducing the probability for human error. The hand-held tablets also provide the benefits of complex case management tools, the ability to

generate ID codes for youth respondents for linking adult and youth data, and secure electronic transfer of data.

4. Efforts to Identify Duplication and Use of Similar Information

FDA's youth tobacco prevention campaign efforts are new. To date, there have been no in-depth evaluations of these campaigns in a real-world setting, and there are no existing data sources that contain measures on awareness of and exposure to the campaigns. This information collection therefore does not duplicate previous efforts. In designing the data collection activities, we have taken several steps to ensure that this effort does not duplicate ongoing efforts and that no existing data sets would address the study questions. We have carefully reviewed existing data sets to determine whether any are sufficiently similar or could be modified to address FDA's need for information on the effectiveness of the campaigns to prevent or reduce youth tobacco use. We investigated the possibility of using existing data to examine our research questions, such as data collected as part of ongoing national surveillance systems, evaluations of current or past state-level campaigns for youth, the National Youth Tobacco Survey, the Youth Risk Behavior Surveillance System, and the Population Assessment of Tobacco and Health. Due to the timing of the campaigns, none of these existing data sources can adequately meet the data collection needs of the campaign evaluations.

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. Consequences of Collecting the Information Less Frequently

Participants in this evaluation are surveyed on an occasional basis. While there are no legal obstacles to reduce burden, lack of information needed to evaluate the FDA's youth tobacco prevention campaigns may impede the federal government's efforts to improve public health. Without the information collection requested for this evaluation study, it would be difficult to determine the value or impact of the campaigns on the lives of the people they are intended to serve. Failure to collect these data could reduce effective use of FDA's program resources to benefit youth in the United States. Careful consideration has been given to how frequently the campaigns' intended audience should be surveyed for evaluation purposes. We believe the longitudinal evaluation design will provide sufficient data to evaluate the campaigns effectively.

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 the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register on May 17, 2019 (84 FR 22499). FDA received four public comments not related to PRA.

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

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The following individuals outside the agency have been consulted on questionnaire development. Additionally, input has been solicited and received from FDA on the design of this study, including participation by FDA in meetings with OMB.

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9. Explanation of Any Incentive or Gift to Respondents

Youth participants in the Cohort 2 evaluation are offered a \$20 incentive for completion of the baseline survey. At each follow-up, youth participants are offered a \$25 incentive to complete the survey online during the 3-week early release period. If participants complete the survey after the early release period, they are offered a \$20 incentive for completing the survey online or in-person. We estimated that the baseline survey takes 30 - 45 minutes to complete, and each follow-up survey takes 45 minutes to complete, on average. The child's parent or guardian does not receive an incentive for completing the baseline interview. (see Exhibit 1)

The study incentives are intended to recognize the time burden placed on participants, encourage their cooperation, and convey appreciation for contributing to this important study, and are comparable to incentives offered for most surveys of this type. Studies suggest that this incentive approach increases response rates and reduces costs. Numerous empirical studies have shown that incentives can significantly increase response rates in cross-sectional surveys and reduce attrition in longitudinal surveys (e.g., Abreu & Winters, 1999; Castiglioni, Pforr, & Krieger, 2008; Jäckle & Lynn, 2008; Shettle & Mooney, 1999; Singer, 2002). The decision to use incentives for this study is based on the need to ensure high retention from baseline to follow-up in order to retain the necessary analytic power of the longitudinal sample. A more detailed justification for the use of incentives is provided in Attachment 5.

The use of modest incentives is expected to enhance survey response rates without biasing responses. A smaller incentive would not appear sufficiently attractive to

participants. We also believe that the incentives will result in higher data validity as participants will become more engaged in the survey process. This will also enhance overall response to the baseline and follow-up surveys. The use of incentives will help ensure that baseline data collection is completed in a timely manner and potentially reduce the number of follow-up visits needed to contact nonrespondents. The specific amount of the proposed incentive is based on several previous projects conducted by RTI, including the National Survey of Child and Adolescent Well-Being, which found that use of similar incentives increased response rates among youth, particularly for retention in longitudinal studies.

Exhibit 1. Incentive Type and Amount

Type of Incentive	Participant	Amount/Value	Total Amount for Completing all Waves
Youth Follow-up Questionnaire incentive, Early Release Period: Online completion during initial three weeks of data collection	All longitudinal panel members (3 follow-up waves)	\$25/survey	\$75
Youth Follow-up Questionnaire incentive: Online or in-person completion after Early Release Period expires	All longitudinal panel members (3 follow-up waves)	\$20/survey	\$60

10. Assurance of Privacy Provided to Respondents

In developing this study, CTP consulted the FDA Privacy Officer to identify potential risks to the privacy of participants and other individuals whose information may be handled by or on behalf of FDA in the performance of this study. Prior to consulting the Privacy Officer, CTP had intentionally designed the study to minimize privacy risks in keeping with the Fair Information Practice Principles (FIPPs) and applying controls selected from the National Institute of Standards and Technology (NIST), Special Publication 800-53, *Security and Privacy Controls for Federal Information Systems and Organizations*. CTP has also identified privacy compliance requirements and coordinated with FDA’s Privacy Officer to ensure responsible offices in CTP satisfy all requirements. The FDA Privacy Office is currently reviewing the Privacy Impact Assessment.

PII Collection

As part of this study, RTI International, the contractor acting on behalf of FDA, is collecting and maintaining personally identifiable information (PII) about participants who complete the mail screener, in-person screener, and in-person and online surveys at baseline and follow-up. The mail screener, completed by the parent, does not collect any PII. However, parents are asked to provide information on the number of adults and

children in the household; their gender, race/ethnicity, and age (to determine eligibility); language spoken in the home; and internet access. As part of the in-person screener to confirm eligibility, parents are asked to provide the following PII: parent's first and last name, e-mail address and phone number of parent and youth participant. The following non-PII is also collected from parents: education level, gender, race/ethnicity, and zip code. As part of the baseline interview, parents provide the following PII: date of birth, first and last name, and phone number for quality control purposes so the study team can verify that the interview took place, if needed. Non-PII collected in the parent baseline interview includes race/ethnicity, household income, marital status, employment status, and education level. Youth participants are asked to provide their first and last name, date of birth, gender, race/ethnicity, grade in school, home address, and phone number as part of the baseline and follow-up surveys. Youth participants who complete the follow-up surveys online are also asked to provide their email address so the study team can send them a virtual gift card incentive for completing the survey.

Addresses for the mail screener are obtained from RTI's address-based sampling frame, which is used to identify households likely to have eligible youth. The foundation of the address-based sampling frame is acquired from the U.S. Postal Service Computerized Delivery Sequence file and then is enhanced by appending ancillary information from public and private sources to better characterize households. Addresses of participants enrolled in the study are maintained so that they can be invited to participate in later follow-up waves of the study.

RTI assigns each household a randomly generated unique 8-digit case identification number (Case ID). A new Case ID is generated with each wave of data collection, with all digits remaining the same except for the sixth digit that designates the data collection wave. This CASE ID can be used by youth participants to access the online survey along with a password assigned by RTI. The password cannot be changed by the participant but is changed by RTI at each wave. Only authorized RTI project staff are granted access to files and systems that connect study respondents and their survey responses to their Case IDs. At each follow-up wave, RTI provides a link to the password-protected study website and unique Case ID to study households via a study mailing, survey email invitation, reminder letter, and three reminder emails so youth can complete the survey online.

Privacy Act Applicability

The information collection is not subject to the Privacy Act of 1974. Hence, no Privacy Act Statement is required to be displayed on the form, website, mobile application or other point at which individuals submit their information.

Data Minimization

The PII collected for this study is limited to the minimum necessary to achieve the authorized purpose and produce a valid study. The purpose of the study is to evaluate *The Real Cost* public education campaign to reduce and prevent tobacco use being conducted by CTP in support of its mandate to positively impact public health. The PII is necessary in order to determine household eligibility, contact parents for scheduling

baseline interviews and follow-up surveys, invite youth participants to participate in follow-up survey waves and obtain parent permission for their participation, conduct quality control checks, and distribute incentives.

Likewise, any potentially sensitive information gathered from participants in association with their PII is limited to that which is essential for the study, such as tobacco use and home tobacco environment. Items such as media use and sensation seeking are collected because they are established risk factors for tobacco use in youth.

FDA has minimized the risk of unnecessary access, disclosure, use or proliferation of PII about participants. FDA and other parties involved in the study maintain study records containing PII only as long as required (for 3 years after final payment of the contract in accordance with FAR Subpart 4.7). RTI International uses an 8-digit unique case identification number to identify participants. Access to PII is restricted by role to personnel who must access this information. Sensitive records are kept in a secure location until destruction occurs. RTI has in place standard operating procedures based on RTI Policy to ensure the security and privacy of recorded information during all phases of the destruction process, including pickup and transport of records from RTI's locations to the destruction site. Non-identifiable or de-identified data (i.e., responses to the study, but without any PII) will be sent by RTI to FDA. No PII will be sent to or be accessible by FDA at any time. Field interviewers and field supervisors sign a detailed data collection agreement at the time they are hired onto the project. This data collection agreement, amongst other things, states that they agree to treat as confidential all information obtained during the interviews or obtained during the course of completing their project-related activities.

Youth participants who complete the online survey provide their email address, so they can receive a virtual gift card incentive. RTI study staff provide an encrypted file with the participants' email addresses to the incentive provider group at RTI so that incentives can be distributed via email. RTI does not share this information with FDA. RTI shares Case ID, password, parent first and last names, youth first name, and household mailing addresses with the print vendor for the initial mail screener, panel maintenance letters, invitation letters, and reminder letters for future waves of the survey. This information is sent to the printer vendor via encrypted files. RTI does not share this information with FDA. The print vendor does not have access to any other PII or non-PII from the study.

RTI International will not share PII gathered via this collection with any other individuals or entities.

Notice and Transparency

All participants are provided notice regarding the collection and use of the information they provide. The purpose of the study and intended use of the information collected is described on the first page of the mail and in-person screeners. In both the mail and in-person screener, parents are told that the information collected will determine their household's eligibility for the study and must provide their consent to complete the

baseline interview, as well as their permission for their child to complete the baseline survey. Youth participants who complete the in-person baseline survey and the follow-up surveys (in-person or online) must first read and accept an electronic informed assent form before they can complete the survey. Youth participants who turn 18 during the course of the study must read and accept an electronic informed consent form. All study materials and website pages are clearly branded as FDA products.

Individual Participation and Control

Participation in the Cohort 2 evaluation of the General Market Youth Tobacco Prevention campaign is entirely voluntary. Participants may choose to not join the study and are free to withdraw at any time without incurring any negative consequences. For all parent consent, parent permission, and youth assent and youth consent forms, affirmative assent or consent is obtained electronically by clicking an “accept” radial button below the electronic assent text on the study tablet or laptop.

Third-Party Accountability

RTI is held accountable for complying with privacy and security procedures (including reporting data breaches) by its contract with FDA, which requires that RTI complies with 45 CFR part 46 and with the contractor’s current Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. RTI agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR part 46 and the Assurance of Compliance. RTI also has an established protocol in place for privacy breaches that includes the Project Director notifying RTI’s IRB and CTP, who, in turn, notifies FDA’s IRB. In addition, RTI has an Incident Response and Breach Notification Plan in place that activates first responders when an incident occurs, and, as required by law, a breach notification policy with respect to protected health information. RTI subcontractors are accountable via contract terms for all data that it handles, uses, shares and maintains as part of this survey.

Data Security

RTI International’s data security procedures for the Federal Information Processing Standards (FIPS) Low network, which is the RTI network on which the data from the evaluation will be stored, have been reviewed by a FedRAMP certified Third Party Organization and deemed acceptable. This organization issued an Authorization to Operate (ATO) for the FIPS Low network.

RTI’s Institutional Review Board (IRB) will review and approve the permission, consent, and assent forms (Attachments 6_E2b3, 6_E2c2, 6_E2d) for the Cohort 2 evaluation. These forms include language for parental permission and youth assent (under age 18) or consent (18 or older). The IRB’s primary concern is protecting respondents’ rights, one of which is maintaining the privacy of respondent information to the fullest extent of the law.

Concern for privacy and protection of respondents’ rights plays a central part in the implementation of the Cohort 2 evaluation and will receive the utmost emphasis.

Interviewers are thoroughly educated in methods for maximizing a respondent's understanding of the government's commitment to privacy to the fullest extent of the law. Several procedures ensure that participants' rights are protected. First, the interviewer introduces himself or herself and the study to the parent/guardian using the Introduction and Informed Consent Scripts, reading the scripted text aloud. All consenting documents include an explanation of the Certificate of Confidentiality (CoC). This text explains that the CoC provides legal protection for respondent information, and outlines contexts in which youth information may or may not be shared. The text specifically notes that the CoC does not affect federal, state or local reporting requirements such as reporting of child abuse, communicable diseases, and threats to harm self or others. The text also explains that Personally Identifiable Information (PII) will not be disclosed. During the process for obtaining informed consent, respondents are given a Study Description (Attachment 8_E2b), which includes information on their rights as study participants. Specifically, the Study Description states that respondents' answers will be used only by authorized personnel for statistical purposes and cannot be used for any other purpose. Parental permission is obtained from the youth's parent or guardian; subsequently, youth assent is requested. Youth who turn 18 during the course of the study provide their own consent. Signed consent and assent are waived in this study.

After obtaining informed assent or consent, field interviewers make every attempt to secure an interview setting in the respondent's home that is as private as possible. In addition, the interview process, by design, includes techniques to afford privacy for the respondent. The self-administered portion of the interview maximizes privacy by giving control of the interview directly to the respondent. This allows the respondent to read the questions directly from the computer screen and then key his or her own responses into the computer via the keyboard.

At least every 48 hours, data are electronically transferred to RTI's servers via secure encrypted data transmission. Once the data are securely transmitted from the field to RTI, cases and all associated information are removed from the laptop. Names, email addresses, phone numbers, and mailing addresses are never transmitted to FDA/CTP. Only authorized RTI staff will have access to this information on a need-to-know basis.

Security for youth participants who complete the follow-up surveys online is assured in a number of ways: (1) parental permission is required for all eligible youth prior to completing the follow-up survey; (2) participants log onto the study's secure server hosted by RTI using a unique identifier and password; (3) participants are provided with information about the privacy of their data before they encounter the first survey item; (4) respondents are asked to provide their assent or consent to participate before they encounter the first survey item; and (5) participants have the option to decline to respond to any item in the survey for any reason. All study staff who handle or analyze data are required to adhere to RTI's standard data security policies.

To ensure data security, all RTI project staff are required to adhere to strict standards. RTI maintains restricted access to all data preparation areas (i.e., receipt and coding). All data files on multi-user systems are under the control of a database manager, with access

limited to project staff on a “need-to-know” basis. No respondent identifiers will be contained in reports to FDA, and results will only be presented in aggregate form.

Implementation of data security systems and processes occur as part of the survey data collection. Data security provisions involve the following:

- All data collection activities are conducted in full compliance with FDA regulations to maintain the privacy of data obtained from respondents and to protect the rights and welfare of human research subjects as contained in their regulations. Respondents receive information about privacy protections as part of the informed consent process.
- All data collectors are trained on privacy procedures and are prepared to describe them in full detail, if necessary, or to answer any related questions raised by respondents. Training includes procedures for safeguarding participants’ information in the field, including securing hardcopy case materials and laptops in the field, while traveling, and in participant homes, and protecting the identity of study participants.
- All field interviewers sign a privacy agreement that emphasizes the importance of respondent privacy and describes their obligations.
- All field staff laptop computers are equipped with encryption software so that only the user or RTI administrators can access any data on the hard drive even if the hard drive is removed and linked to another computer.
- Laptops use the Microsoft Windows operating system and require multiple valid login IDs and passwords to access any applications or data.
- All data transferred to RTI servers from field staff laptops is encrypted and transferred via a secure (SSL) broadband connection or optionally a secure telephone landline. Similarly, all data entered via the study’s web-based survey is encrypted, as the responses will be on a website with an SSL certificate applied. Data are passed through a firewall at RTI and then collected and stored on a protected network share on the RTI Network. Only authorized RTI project staff members have access to the data on the secure network share.
- Participants access the online follow-up surveys with a unique Case ID and password and complete the survey on a secure server online.

All respondents are assured that the information they provide is maintained in a secure manner and will be used only for the purpose of this research. Respondents are assured that their answers will not be shared with family members and that their names will not be reported with responses provided. Respondents are told that the information obtained from all surveys will be combined into a summary report so that details of individual surveys cannot be linked to a specific participant.

Respondents participate on a voluntary basis. The voluntary nature of the information collection is described in the introductory section of the consent process (Attachments 6_E2b3, 6_E2c2, 6_E2d) and the lead letter (Attachment 10_E2e).

11. Justification for Sensitive Questions

The majority of questions asked are not of a sensitive nature. There are no requests for a respondent's Social Security Number. However, it is necessary to ask some questions that youth may consider sensitive to assess specific health behaviors such as cigarette smoking. These questions are essential to the objectives of this information collection. Questions about messages concerning lifestyle (e.g., smoking, current smoking behavior, attempts to quit smoking) and some demographic information, such as race, ethnicity, and income, could be considered sensitive as well. To address concerns about potential inadvertent disclosure of sensitive information, respondents are fully informed of the applicable privacy safeguards. The informed consent protocol (Attachments 6_E2b3, 6_E2c2, 6_E2d) informs participants that potentially sensitive questions will be asked in the survey. The evaluation employs several procedures to minimize potential negative reactions to potentially sensitive questions, including the following:

- Respondents are informed that they can skip any question that makes them uncomfortable or that they do not wish to answer.
- Web surveys are self-administered and maximize respondent privacy without the need to verbalize responses.
- Participants are provided with a toll-free phone number to call RTI's IRB Office if they have a question or concern about a sensitive issue.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA previously requested and received approval to develop and survey a second longitudinal cohort (Cohort 2), which consists of a new sample of youth ages 11-16 at baseline. The Cohort 2 baseline and first follow-up surveys are complete. Two additional follow-up surveys are planned for Cohort 2. We expect a total of 6,270 youth participants to complete the follow-up surveys for a total burden of 7,327 hours.

Exhibit 2. Estimated Annual Reporting Burden¹

Table 1--Estimated Annual Reporting Burden¹

Type of Respondent	Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
General Population	Screener and Consent Process (Parent Permission)	6,270	1	6,270	.125(7.5 minutes)	784
Parent of Youth Baseline Survey Participants	Telephone Verification Survey	627	1	627	.1333 (8 minutes)	84
	Recruitment Materials – Panel Maintenance letter, Lead letter, Survey Invitation email, Q&As; Study Description; Email Reminders, Reminder Letter, Notifications	6,270	1	6,270	.20 (12 minutes)	1,254

Cohort 2 Youth Assent	Youth Assent under 18	5,874	1	5,874	.08 (5 minutes)	470
Cohort 2--Youth Aged 11 to 18	Youth Consent 18 and up	396	1	396	.08 (5 minutes)	32
	Cohort 2--Youth 1st, 2nd, 3rd Follow-Up Questionnaire	6,270	1	6,270	0.75 (45 minutes)	4,703
Totals				0		0

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. RTI has conducted many smoking-related surveys of similar length among youth. We have examined diagnostic data from each of these prior surveys and estimate that data collection for the follow-up surveys will take 45 minutes per respondent, on average. According to the U.S. Department of Labor’s Bureau of Labor Statistics, as of June 2019 the national average hourly wage is \$27.90. Thus, assuming an average hourly wage of \$27.90, the estimated one-year annualized cost to participants will be \$131,213.70. The estimated value of respondents’ time for participating in the information collection is summarized in Exhibit 3.

Exhibit 3. Estimated Annual Cost

Type of Respondent	Activity	Annual Burden Hours	Hourly Wage Rate	Total Cost
Cohort 2--Youth Aged 11 to 18	Cohort 2—Youth 1st, 2 nd , 3 rd Follow-Up Questionnaire	7,327	\$27.90	\$204,423.30
Total		7,327		0

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

This information collection is funded through a contract with RTI. The total estimated costs attributable to this data collection is \$12,641,919 (Exhibit 4). 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 and its media contractor, evaluation plan development, instrument development, reporting, RTI IRB, and progress reporting and project management. This information collection will occur from December 2019 through October 2020.

Exhibit 4. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-13	15%	\$99,172	\$14,876
GS-13	25%	\$102,477	\$25,619
GS-15	5%	\$137,849	\$6,892
		Total Salary Costs	\$47,387
		Contract Cost	\$ 12,594,532
		Total	\$12,641,919

15. Explanation for Program Changes or Adjustments

FDA has revised the burden due to the decision to complete data collection for the Media Tracking Survey. Therefore, the estimated burden hours for the 1) Screener and Consent Process, 2) Parent Baseline Questionnaire, 3) Media Tracking Screener, and 4) three waves of Media Tracking Questionnaires are no longer needed or requested. In addition, we have completed the baseline and first wave of follow-up data collection for Cohort 2 of the General Market campaign evaluation. The associated burden for those activities has been removed for this extension. This resulted in a decrease of 97,683 responses and 18,386 hours (from the currently approved 123,390 responses and 25,713 hours). The remaining burden to complete the final rounds of data collection is estimated to be 25,707 respondents/annual responses and 7,327 hours.

Additionally, FDA added two question to the survey after submission to OMB. As part of our evaluation study, it is important that we identify youth in the data who may be exclusively vaping marijuana vs. e-cigarettes with nicotine. The rationale for this is that the e-cigarette beliefs of youth who exclusively vape marijuana products may be different and may not be impacted by FDA’s campaign in the same way as regular e-cigarette users. It is important for us to track those potential differences. Also, it is important for us to understand the impact of FDA’s campaign on e-cigarette experimenters vs. established users. Differentiating between the two groups will help us better understand the campaign’s impact(s). We currently already ask about both products in the survey, but these questions provide more specificity

16. Plans for Tabulation and Publication and Project Time Schedule

Data from this information collection will be used to estimate awareness of and exposure to the campaigns among youth. These estimates will take the form of self-reported ad recognition and recall that assess basic exposure as well as frequency of ad exposure. These estimates will also be calculated separately for each specific campaign advertisement.

Data from this information collection will also be used to examine statistical associations between exposure to the campaigns and pre-post changes in specific outcomes of interest. This will be accomplished with the use of multivariate models that estimate follow-up measures of each relevant outcome as a function of prior self-reported exposure to the campaign, controlling for baseline measures of each outcome as well as baseline individual characteristics that may confound the relationship between campaign exposure and changes in outcomes. The primary outcomes of interest among youth will be awareness of the campaigns as well as tobacco-related beliefs, attitudes, intentions and behaviors. We hypothesize that there should be larger changes in outcomes among individuals who are exposed to the campaigns more frequently (i.e., dose-response effects).

We will also utilize measures of market-level campaign intensity, which will be constructed with available data on campaign gross rating points (GRPs) for each market covered by this evaluation. These data provide an overall measure of the reach and frequency of televised programming (in this case, campaign ads) within any given media market. These data will be merged with the survey data to provide an additional measure of campaign exposure among study participants. This will allow us to analyze the relationship between the market-level delivery of the campaigns and actual levels of awareness in each sample that is collected. This will also facilitate further analyses of the relationship between exogenous market-level measures of campaign dose and changes in the aforementioned outcome variables of interest.

The reporting and dissemination mechanism will consist of three primary components: (1) summary statistics (in the form of PowerPoint presentations and other briefings) on individual awareness of and reactions to the campaign, (2) a comprehensive evaluation report summarizing findings from this information collection, and (3) at least three peer-reviewed journal articles that document the relationships between campaign exposure and changes in the aforementioned outcomes of interest. The key events and reports to be prepared are listed in Exhibit 5.

The next round of data collection (Cohort 2, second follow-up) is scheduled to begin in December 2019. Therefore, OMB approval is requested as soon as possible.

Exhibit 5. Project Schedule

Project Activity	Date	Status
Cohort 1, Baseline data collection: experimenter and non-trier youth	November 2013 to March 2014	Complete
Cohort 1, First Follow-up data collection: experimenter and non-trier youth	August through October 2014	Complete
Cohort 1, Second Follow-up data collection: experimenter and non-trier youth	April through July 2015	Complete
Cohort 1, Third Follow-up data collection: experimenter and non-trier youth	January through March 2016	Complete
Cohort 1, Fourth Follow-up data collection: experimenter and non-trier youth	August through October 2016	Complete
Cohort 2, Baseline data collection: experimenter and non-trier youth	June through October 2018	Complete
Cohort 2, First Follow-up data collection: experimenter and non-trier youth	April through June 2019	Complete
Cohort 2, Second Follow-up data collection: experimenter and non-trier youth	December 2019 through February 2020	Not Approved
Cohort 2, Third Follow-up data collection: experimenter and non-trier youth	August 2020 through October 2020	Not Approved
Baseline data collection: rural smokeless with male youth	January 2016 through April 2016	Complete
First Follow-up data collection: rural smokeless with male youth	September 2016 through December 2016	Complete
Second Follow-up data collection: rural smokeless with male youth	May 2017 through August 2017	Complete
Third Follow-up data collection: rural smokeless with male youth	January 2018 through March 2018	Complete
Preparation of analytic data file	Approximately 2–4 weeks after completion of data collection	
Data analysis	Approximately 5–12 weeks after completion of each analytic data file	
Report writing and dissemination	Approximately 12-16 weeks after completion of each analytic data file	

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

Not applicable. There are no exceptions to the certification statement.