Evaluation of the Food and Drug Administration's Tobacco Public Education Campaign

0910-0753

SUPPORTING STATEMENT

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) (Attachment 1), 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. Accordingly, FDA will implement multi-strategy youth-targeted public education campaigns to reduce the public health burden of tobacco that will consist of 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.

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 (CDC) Office on Smoking and Health (OSH), which has experience implementing and evaluating national anti-tobacco media campaigns. FDA will implement youth tobacco prevention campaigns, which are currently under development and will include evidence-based paid media advertising that highlights the negative health consequences of tobacco use. The objective of the evaluation is to measure the effectiveness of CTP public education campaigns designed to reduce tobacco use among general market youth aged 12 to 17. FDA's general market youth prevention campaigns will focus on reducing tobacco use in the following audience segments: (1) youth who have not tried FDA-regulated tobacco products (non-triers), (2) youth who are intermittent users of FDA-regulated tobacco (experimenters), and (3) youth in rural areas who are susceptible to or use smokeless

tobacco products. The goal of the proposed 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.

This study 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 assess their impact on outcome variables of interest. The primary outcome study will rely on in-person data collection and Web surveys to be self-administered on personal computers. The baseline survey of youth and their parent/guardian for the experimenter and non-trier campaigns will be fielded from November 2013 to January 2014. The baseline household data collection will occur over a 3-month period, with the majority of data collection occurring in the first 2 months. The baseline fielding period of male youth and their parent/guardian for the rural smokeless campaign will occur between December 2015 and July 2016, and use instruments and documents tailored to the campaign and target audience. Otherwise, all data collection methods and procedures are identical to the non-trier and experimenter campaigns. Youth in the study will complete three follow-up surveys at 8-month intervals following baseline data collection. The follow-up surveys will be conducted largely in person (70%), with the remainder (30%) conducted via a Web-based survey. This design will facilitate analysis of relationships between individuals' exposure to the campaigns and pre-post changes in outcomes of interest. This longitudinal design allows us to calculate baseline-to-follow-up changes in campaign-targeted outcomes for each study participant. 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 will be aged 11 to 16 at baseline and 13 to 18 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. As the cohort will be aging over this time period, the data collected throughout the study will reflect information from youth aged 11 to 18.

In addition to the outcome evaluation surveys, we also plan to complete three Web-based media tracking surveys to better understand awareness of and receptivity to campaign materials among youth subpopulation groups of interest (e.g., gender, age, geographic area). Research studies have demonstrated that receptivity to advertisements is causally antecedent to actual ad effectiveness (e.g., Davis et al., 2013; Davis, Uhrig, et al., 2011; Dillard, Shen, & Vail, 2007; Dillard, Weber, & Vail, 2007). Surveys will be conducted 4 months after campaign launch and at 8-month intervals throughout the evaluation period. The proposed surveys will provide early indicators of the campaign's reach and resonance with specific youth subpopulations of interest. A new sample for the tracking study is necessary because more frequent surveys of the outcome evaluation could introduce unintended bias in their responses (i.e., panel conditioning).

The outcome baseline survey will include measures of tobacco-related beliefs, attitudes, intentions, and behaviors. The outcome follow-up surveys will include measures of audience awareness of and exposure to the campaign advertisements as well as the aforementioned outcome variables of interest. The baseline and follow-up questionnaires

are presented in Attachment 2. The rationale for use of these specific measures is in Attachment 2a. The tracking survey will assess awareness of the campaigns and receptivity to campaign messages throughout the campaign; similar measures of beliefs, attitudes, intentions, and behavior are also critical in the survey in order to examine awareness across subgroups and to assess comparability with the representative outcome survey. As part of the outcome evaluation study, a baseline survey will also be conducted with the parent or legal guardian of each youth baseline survey participant to collect data on household characteristics and media use (Attachment 3). Tracking survey data will not be used to make statistical inferences about the U.S. population of youth. The media tracking survey is located in Attachment 4. Further rationale for conducting media tracking can be found in Attachment 4a.

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 will rely 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 intention 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 to be met: (1) reasonable randomness in the media delivery at the market level and (2) a sufficient amount of variation in TRPs to identify statistical relationships between the 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 sufficient variation in media delivery across markets will exist and can be used to test hypotheses based on TRPs.

A second measure of campaign exposure, self-reported exposure, may be used to examine campaign effects given the limitations of market-level exposure measures. Self-reported recall of campaign ads will be measured at the individual level. 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 which mitigating the limitations of one approach in isolation.

2. Purpose and Use of the Information Collection

The information obtained from the proposed data collection activities is collected from individuals or households and 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 proposed 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 will consist of a baseline interview and several follow-up interviews with selected parents and youth. The in-person baseline household data collection for parents and youth will occur over a 3-month period, with the majority of data collection occurring in the first 2 months. Three longitudinal follow-up surveys will occur in 8-month intervals following the baseline data collection. The follow-up surveys will be conducted largely in person (approximately 70%), with the remainder conducted via a Web-based survey (approximately 30%). Eligible youth will be aged 11 to 16 at baseline and 13 to 18 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. In addition, three waves of a media tracking survey with a convenience sample of U.S. youth will be gathered between waves of the primary longitudinal data collection. All tracking surveys will be conducted by RTI International using a convenience sample purchased from the digital data collection company Global Market Insite, Inc. (GMI). GMI will provide youth respondents for three unique, cross-sectional surveys while

allowing RTI to manage the survey fielding and data collection on GMIs secure server. The baseline experimenter and non-trier campaign surveys will include youth aged 11 to 16 in 75 U.S. markets, at waves 2, 3, and 4 expecting an 80% response rate.

The baseline rural smokeless campaign surveys will include male youth aged 11 to 16 in 30 rural media markets with waves 2, 3, and 4 expecting an 80% response rate. As the cohort will be aging over this time period, the data collected throughout the study will reflect information from youth aged 11 to 18.

The cross-sectional media tracking surveys will include youth aged 13 to 17 in the United States in each of three waves.

3. Use of Improved Information Technology and Burden Reduction

This outcome study will rely 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 which will be 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 to fulfill the agency's requirement or request.

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 will also use hand-held tablets to conduct household screening interviews and collect adult data. 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 computers also provide the benefits of complex case management tools, ability to generate ID codes for youth respondents which will be used to link adult and youth data, and quick, 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 has been no in-depth evaluation 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 proposed information collection therefore does not duplicate previous efforts. In designing the proposed 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 proposed study questions. We have 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 the effectiveness of the campaign with respect to reducing youth tobacco initiation. 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 will be able to provide the necessary data collection needs of the campaigns.

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

Respondents to this collection of information will answer on an occasional basis. While there are no legal obstacles to reduce burden, any lack of information needed to evaluate the Tobacco Public Education Campaign 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 that the proposed longitudinal survey and tracking survey 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 CRF 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 June 21, 2013 (78 FR 37546) FDA received two public comments that were not related to the information collection. The first comment, submitted by a private citizen, does not agree with the government spending money on campaigns like this. The comment does not go in detail or provide any alternatives for conducting this study. The second comment, from a tobacco advocacy group for reducing tobacco use, is a letter of support for FDA to gain approval to conduct this study. Both comments did not contain any information related to the Paperwork Reduction Act, and therefore, are beyond the scope of this collection.
The following individuals inside the agency have been consulted on the design of the campaign evaluation plan, audience questionnaire development, or intra-agency coordination of information collection efforts:

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The following individuals outside of the agency have been consulted on questionnaire development. FDA CTP has also participated in meetings with CDC OSH throughout 2013 with updates on CTP campaign activities. 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

For respondents to the media tracking survey, GMI will provide non-monetary "MarketPoints," which are part of panel maintenance strategies for their panel, which participants can trade for material items with GMI partner vendors (e.g., Amazon.com and Starbucks) or for cash. MarketPoints are valued at approximately $10 per survey.

Households that receive the mail screener inviting them to participate in the male rural smokeless study will all receive a nominal incentive of a $2 bill to encourage participating in this brief survey. A meta-analysis of studies examining the use of incentives in mail surveys showed that pre-paid incentives and promised incentives increase participating in mail surveys by 19% and 8% respectively, compared to no incentives (Church, 1993). More recent studies confirm these findings (e.g., Montaquila et al., 2013; Brick et al., 2012; Beebe et al., 2005).

Parents or legal guardians of participants in the outcome evaluation study will not receive incentives. However, youth participants in the outcome evaluation surveys will receive incentives. Youth participants will be offered a $20 incentive for completion of the baseline survey. At follow-up, respondents will be offered a $25 incentive to complete the survey online during an early release period running through July 21st. A $20 incentive will be offered to respondents for completing the survey after July 21st, whether online or in-person. Studies suggest that this incentive approach will increase response rates and reduce costs. We estimate that the baseline survey will take 30 minutes to complete, and the follow-up survey will take 45 minutes. The 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 similar to incentives that are offered for most surveys of this type. 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. It is crucial that the baseline survey be completed prior to the launch of the campaigns as this is central to our planned data analyses. 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 (see Exhibit 1).

Exhibit 1. Incentive Type and Amount

Type of Incentive	Participant	Amount/Value	Total Amount for Completing all Waves
Youth Media Tracking incentive	Youth selected through GMIs adult panel (*not* longitudinal panel members)	A nonmonetary incentive valued at approximately $10	A nonmonetary incentive valued at approximately $10
Household mail screener incentive	An adult household member	$2 / household	$2
Youth Baseline Questionnaire incentive	All longitudinal panel members	$20/survey	$20
Youth Follow-up Questionnaire incentive-Early Release Period: Online completion during the initial three weeks of data collection	All longitudinal panel members (up to 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 (up to 3 follow-up waves)	$20/survey	$60

10. Assurance of Privacy Provided to Respondents

RTI's Institutional Review Board (IRB) will review and approve the protocols and consent forms for the outcome evaluation survey and media tracking survey prior to any respondent contact (Attachments 6a, 6b, 6c and 6d). 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 will play a central part in the implementation of the outcome evaluation study and will receive the utmost emphasis. Interviewers will be 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 respondents' rights are protected. First, the interviewer introduces himself or herself and the study to potential adult respondents using the Introduction and Informed Consent Scripts (Attachments 6a, 6b, 6c, 6d and 7), reading the scripted text aloud to each adult respondent. As part of the process for obtaining informed consent, respondents are given a Study Description (Attachment 8), 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 consent is obtained from the youth's parent or guardian; subsequently, youth assent is requested. Although full names of youth and adult respondents and contact information will be collected for all respondents, signed consent and assent are waived in this study.

After obtaining informed consent, 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.

Each day they work, interviewers electronically transmit all completed screening and interview data to RTI's servers via secure encrypted data transmission. On the data files, respondents are distinguished only by a unique identifier assigned to screenings and interviews. These identifiers will not be linked with names and will be used to link adult and youth data prior to analysis.

Security for respondents of the Web-based media tracking surveys will be assured in a number of ways: (1) GMI will invite youth panel participants to complete the survey through an invitation to their parents asking for their consent to have their child's opinions, which is fully compliant with COPPA's revised standards; each respondent will remain completely anonymous and will be known only by a unique alphanumeric variable; (2) participants will log onto GMI's secure server using a link provided by GMI and this unique identifier, with the result that no information about the respondent's identity will be downloaded to or housed on RTI's server; (3) respondents will be provided with information about the privacy of their data to the fullest extent of the law before they encounter the first survey item; (4) respondents will be required to provide their assent to freely participate before they encounter the first survey item; (5) respondents will have the option to decline to respond to any item in the survey for any reason; and (6) GMI will deliver non-monetary compensation. All those who handle or analyze data will be required to adhere to the standard data security policies of RTI.

To ensure data security, all RTI project staff are required to adhere to strict standards and to sign a nondisclosure agreement as a condition of employment on this project. RTI maintains restricted access to all data preparation areas (i.e., receipt and coding). All data files on multi-user systems will be under the control of a database manager, with access limited to project staff on a "need-to-know" basis only. A detailed description of privacy safeguards is provided with this submission (Attachment 9). 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 will occur as part of the survey data collection. Data security provisions will involve the following:

- All data collection activities will be 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 will receive information about privacy protections as part of the informed consent process.
- All data collectors will be trained on privacy procedures and be prepared to describe them in full detail, if necessary, or to answer any related questions raised by respondents. Training will include procedures for safeguarding sample member information in the field, including securing hardcopy case materials and laptops in the field, while traveling, and in respondent homes, and protecting the identity of sample members.
- All project employees will sign a privacy agreement that emphasizes the importance of respondent privacy and describes their obligations.
- Access to the file linking respondent identifiers and item data with their contact information will be limited to project staff who have signed the privacy agreement.
- All field staff laptops and tablet computers will be 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 will use the Microsoft Windows operating system and require a valid login ID and password to access any applications or data.
- All data transferred to RTI servers from field staff laptops will be encrypted and transferred via a secure (SSL) broadband connection or optionally a secure telephone (land) line. Similarly, all data entered via the Web-based survey system will be encrypted as the responses will be on a Web site with an SSL certificate applied. Data will be 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 will have access to the data on the secure network share.
- Following receipt from the field, Personally Identifiable Information (PII) will be stored only on RTI password-protected, secured servers. Only authorized project members will have access to PII for research sample members.
- For the outcome evaluation, Web survey respondents will be required to create a unique password to access their survey and, in the event of a break-off, to resume the survey at a later date. At log in, Web respondents will also be required to select and answer one of five security questions that will be used in the event the respondent requests a password re-set after beginning the survey.
- For the media tracking survey, respondents will be given a unique alphanumeric variable and will log onto GMI's secure server using a link provided by GMI and this unique identifier, with the result that no information about the respondent's identity will be downloaded to or housed on RTI's server.

All respondents will be assured that the information they provide will be maintained in a secure manner and will be used only for the purpose of this research (see Attachment 7). Respondents will be assured that their answers will not be shared with family members and that their names will not be reported with responses provided. Respondents will be told that the information obtained from all of the surveys will be combined into a

summary report so that details of individual questionnaires cannot be linked to a specific participant.

Respondents will participate on a voluntary basis. The voluntary nature of the information collection is described in the introductory section of the Screener and Consent Process (Attachments 6 and 7) and the initial lead letter (Attachment 10).

11. Justification for Sensitive Questions

The majority of questions asked will not be of a sensitive nature. There will be no requests for a respondent's Social Security Number (SSN). 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 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, but not highly sensitive. To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards. The informed consent protocol (see Attachments 6a, 6b, 6c and 6d) will apprise respondents that these topics will be covered during 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:

- Respondents 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.
- Participants will be provided with a specific toll-free phone number (linking directly to the RTI IRB Office) to call in case they have a question or concern about the sensitive issue.

Finally, as with all information collected, these data will be presented with all identifiers removed.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the one time reporting burden for this collection to be 37,836. The analogous number in Table 1, 12,612, is a result of dividing by three for the one time burden, to avoid double counting in the ROCIS system

Information will be collected through interviews involving U.S. youth aged 11 to 18 at baseline data collection. Information will be collected at baseline and in three follow-up waves approximately 8 months apart. To better understand youth's awareness of and receptivity to campaign materials between waves of the outcome evaluation, we also plan

to complete 1,333 Web-based surveys in between the 8-month longitudinal surveys with a separate convenience sample. Statistical power estimates provide guidance on reasonable expectations for observing statistically significant change in outcomes of interest as detailed in Section B.1.

Because we anticipate respondent attrition between the baseline and follow-up surveys (approximately 20%), we must collect enough interviews at baseline to yield the desired sample sizes at follow-up waves. Based on data from previous longitudinal studies conducted, we estimate that a total of 13,413 youth respondents and their parent or legal guardian must be contacted through the initial screening and consent process (see Attachments 6a, 6b, 6c and 6d), The estimated burden per response is 10 minutes for an annualized total of 2,280 hours.

For the experimenter and non-trier campaigns, an estimated 2,686 youth will complete the youth baseline questionnaire to yield 2,148 completes at the first follow-up, 1,719 completes at the second follow-up, and 1,375 completes at the third follow-up survey waves (Attachment 2). The estimated burden per response is 30 minutes for each baseline questionnaire, for an annualized total of 1,343 hours. The estimated burden per response is 45 minutes for each follow-up questionnaire, for an annualized total of 1,611 burden hours for the first follow-up, 1,289 hours for the second follow-up, and 1,031 hours for the third follow-up questionnaires.

For the rural smokeless campaign, an estimated 656 youth will complete the youth baseline questionnaire to yield 525 completes at the first follow-up, 420 completes at the second follow-up, and 1,008 completes at the third follow-up survey waves (Attachment 2). The estimated burden per response is 30 minutes for each baseline questionnaire, for a total annualized burden of 328 hours. The estimated burden per response is 45 minutes for each follow-up questionnaire, for a total of 1,182 annualized burden hours for the first follow-up, 315 hours for the second follow-up, and 252 hours for the third follow-up questionnaires.

The parent or legal guardian of youth recruited will also complete the parent baseline questionnaire with an estimate burden per response of 10 minutes, for an annualized total burden of 568 hours (Attachment 3).

To obtain the target number of completes for the media tracking survey, 13,333 respondents will be contacted for each survey wave through an online invitation (Attachment 10). The estimated burden per response is 2 minutes, for a total annualized burden of 400 hours for the first media tracking questionnaire, 400 hours for the second media tracking survey, and 400 hours for the third media tracking survey (Attachment 4). An estimated 1,333 youth will be recruited to complete each of the three waves of the media tracking survey. The estimated burden per response is 30 minutes for each questionnaire, for a total annualized burden of 667 hours for the first media tracking survey, 667 hours for the second media tracking survey, and 667 hours for the third media tracking survey.

This data collection will take place between late 2013 and early 2016. The target number of completed campaign questionnaires for all respondents is 211,859, and the annualized response burden is estimated at 12,612 hours. OMB approval is requested for 3 years. Exhibit 2 provides details about how this estimate was calculated. The Web self-administered surveys will be designed to maximize ease of response (at home on personal computers) and thus decrease respondent burden.

Table 1.--Estimated Annual Reporting Burden[1]

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours[1]
General population	Screener and Consent Process (Youth and Parent)	13,413	1	13,413	0.17	2,280
Youth aged 11 to 18 in the United States (Experimental & Non-Trier)	Youth Baseline Questionnaire (11-16 yrs)	2,288	1	2,288	0.50	1,144
	Youth First Follow-Up Questionnaire (11-16 yrs)	1,965	1	1,965	0.75	1,474
	Youth Second Follow-up Questionnaire (11-16 yrs)	1,719	1	1,719	0.75	1,289
	Youth Third Follow-up Questionnaire (13-18 yrs)	1,375	1	1,375	0.75	1,031
Male youth aged 11 to 18 in U.S. rural markets (Rural Smokeless)	Youth Baseline Questionnaire (11-16 yrs)	656	1	656	0.50	328
	Youth First Follow-Up Questionnaire (11-16 yrs)	525	1	525	0.75	394
	Youth Second Follow-up Questionnaire (11-16 yrs)	420	1	420	0.75	315
	Youth Third Follow-up Questionnaire (13-18 yrs)	336	1	336	0.75	252
Parent of youth baseline survey participants	Parent Baseline Questionnaire	3,342	1	3,342	0.17	568
Youth aged 13 to 17 in the United States	Media Tracking Screener	13,333	1	13,333	0.03	400
	First Media Tracking Questionnaire	500	1	500	0.50	250
	Media Tracking Screener	13,333	1	13,333	0.03	400
	Second Media Tracking Questionnaire	500	1	500	0.50	250
	Media Tracking Screener	13,333	1	13,333	0.03	400
	Third Media Tracking Questionnaire	500	1	500	0.50	250
Total Annualized Hours						0

[1] One time burden, actual burden hours have been divided by 3 to avoid double counting in the ROCIS system

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 this study will take approximately 30 minutes per respondent. According to the U.S. Department of Labor (DOL) Bureau of Labor Statistics as of March 2011 the national average hourly wage is $22.89. Thus, assuming an average hourly wage of $22.89, the estimated one-year annualized cost to participants will be $288,690. 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
General population	Screener and Consent Process (Youth and Parent)	2,280	$22.89	$52,189
Youth aged 11 to 18 in the United States	Youth Baseline Questionnaire	1,343	$22.89	$30,741
	Youth First Follow-Up Questionnaire	1,611	$22.89	$36,876
	Youth Second Follow-up Questionnaire	1,289	$22.89	$29,505
	Youth Third Follow-up Questionnaire	1,031	$22.89	$23,600
Male youth aged 11 to 18 in U.S. rural markets	Youth Baseline Questionnaire	328	$22.89	$7,508
	Youth First Follow-Up Questionnaire	394	$22.89	$9,019
	Youth Second Follow-up Questionnaire	315	$22.89	$7,210
	Youth Third Follow-up Questionnaire	252	$22.89	$5,768
Parent of youth baseline survey participants	Parent Baseline Questionnaire	568	$22.89	$13,002

(continued)

Exhibit 3. Estimated Annual Cost (continued)

Type of Respondent	Activity	Annual Burden Hours	Hourly Wage Rate	Total Cost
Youth aged 13 to 17 in the United States	Media Tracking Screener	400	$22.89	$9,156,
	First Media Tracking Questionnaire	667	$22.89	$15,268
	Media Tracking Screener	400	$22.89	$9,156
	Second Media Tracking Questionnaire	667	$22.89	$15,268
	Media Tracking Screener	400	$22.89	$9,156
	Third Media Tracking Questionnaire	667	$22.89	$15,268
Total		12,612		$288,690

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 are $12,148,807 (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 2013 through 2015.

Exhibit 4. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-13	15%	$89,003	$13,350
GS-13	25%	$94,969	$23,742
GS-15	5%	$123,758	$6,188
		Total Salary Costs	0
		Contract Cost	$12,105,527
		Total	**$12,148,807**

15. Explanation for Program Changes or Adjustments

This is a new data collection.

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 survey. 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 to the survey 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.

Baseline information collection must be completed before the launch of the campaign. OMB approval is requested as soon as possible.

Exhibit 5. Project Schedule

Project Activity	Date
Baseline data collection: experimenter and non-trier youth	November 2013 to January 2014
Follow-up data collection: experimenter and non-trier youth	July 2014–May 2016
Baseline data collection: rural smokeless with male youth	December 2016 – July 2016
Follow-up data collection: rural smokeless with male youth	September 2016 – June 2018
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.