

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), 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 a point-of-sale campaign to reduce the public health burden of tobacco that will consist of a convenience store-based public education campaign targeting adult smokers.

Tobacco use is the leading preventable cause of disease, disability, and death in the United States. More than 480,000 deaths are caused by tobacco use each year in the United States (USDHHS, 2014). Each day in the United States, nearly 2,500 youth under age 18 try their first cigarette (SAMHSA, 2016), and 16 million people have at least one serious illness caused by smoking cigarettes (USDHHS, 2014). 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's) Office on Smoking and Health (OSH), which has experience implementing and evaluating national tobacco-focused public education campaigns. FDA will implement a point-of-sale campaign, which will include paid media advertising that highlights the importance of attempting to quit smoking even after a previous quit attempt. The objective of the evaluation is to measure the effectiveness of the CTP point-of-sale campaign designed to increase motivation to quit among adult smokers aged 25 to 54. 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 campaign. Thirty counties with sufficient media capabilities for the campaign were randomly selected from a list of 37 potential counties for campaign implementation. Of

these, 15 counties were randomly assigned to receive the media intervention, and 15 were randomized to serve as control counties. Participation by retailers in the intervention counties is completely voluntary.

This study is designed to measure awareness of and exposure to FDA's point-of-sale campaign among adults and the campaign's impact on outcome variables of interest. After identifying eligible participants by mail when possible, the study will rely on in-person and online data collection, in addition to 3 optional app-based questionnaires to be self-administered by participants on their personal smartphones and 4 brief telephone verification questionnaires completed by phone to prevent interviewer fraud. We will also audio record 10% of in-person interviews as a quality control measure. After the media intervention is launched in January 2018, we anticipate it will take approximately two months to select all the households, mail them screeners, and receive the completed mail screeners. As a result, we anticipate that Wave 1 of data collection (field screening and evaluation questionnaire completion) will occur from March 2018 through June 2018 (approximately 4 months). Adults in the study will complete three additional questionnaires (either online or in person), over 24 months (approximately 7 months apart). This longitudinal design allows us to calculate changes in campaign-targeted outcomes across time for each study participant. We hypothesize that, if the campaign is effective, there will be significant differences in outcomes between the control and treatment markets. Eligible adults will be aged 25 to 54 at Wave 1 and 27 to 56 by the end of data collection, allowing us to follow the same adults over time and understand cessation for the campaign's target audience of adults aged 25 to 54. The Wave 1, 2, 3, and 4 evaluation questionnaires assess audience self-reported awareness of and exposure to the campaign advertisements and tobacco-related beliefs, attitudes, intentions, and behaviors. The Waves 1, 2, 3, and 4 evaluation questionnaires are presented as Attachments 2a and 2b. The rationale for use of these specific measures is in Attachment 2c.

Although self-reported exposure to tobacco-focused public education campaigns has been widely used to evaluate broadcast and online campaigns, as media environments become increasingly complex and fragmented, it is increasingly challenging for individuals to accurately recall where they have seen campaign messages. Therefore, to complement self-reported measures of campaign exposure, we are inviting participants to use a smartphone app that will capture potential campaign exposure passively. That is, it will allow us to assess how frequently participants visit convenience stores in which FDA's campaign is present. During the Wave 1 evaluation questionnaire, participants will be asked whether they have a smartphone. If they do, the field interviewer will show the participant the consent for the smartphone app-based part of the study (Attachment 3b), which explains that this part of the study is completely voluntary and separate from the Waves 1-4 evaluation questionnaires. Participants will sign this separate consent form if they would like to participate in this part of the study. The consent form describes the app-based component in detail. A list of convenience stores in which the FDA ads are placed and their locations in treatment counties will be given to the app vendor. The creative team will also provide a comparable list of convenience stores in the control communities. The app will record the time and date of visits to these convenience stores.

In addition to tracking store visits, the app will also administer three short questionnaires over 18 months (approximately every 6 months) to provide additional data points for exposure, control, and outcome variables. The app-based questionnaires will assess tobacco use, tobacco purchasing behavior, intention to quit smoking, and campaign awareness (Attachment 4a). App data will not be used to make statistical inferences about the U.S. population of adults. Further rationale for conducting this questionnaire can be found in Attachment 4c. The notifications that will be used to invite participants to complete the app-based questionnaires can be found in Attachment 4d.

The highest standard of evidence for causal relationships between health marketing campaigns and behavior change is the demonstration of differences in behavioral outcomes of interest by media dose (e.g., Farrelly et al., 2005, 2009, 2012). The requested data collection is an evaluation designed to assess the planned media dose of the FDA point-of-sale campaign advertisements across the U.S. The evaluation will rely on a control-treatment evaluation design that leverages variation in exposure to campaign messages across media markets. The effect of the campaign on tobacco-related outcomes will be examined using market-level media dose and self-reported and passive campaign exposure at the individual-level.

The primary hypothesis of this approach is that individuals who reside in media markets assigned to be exposed to the campaign will exhibit a greater motivation and intention to quit smoking. Exogenous market-level doses of media will be measured with advertising gross rating points (GRPs). GRPs are a measure of advertising impact and reflect the availability of advertising space in retail stores. The hypothesis is testable with the use of market-level campaign GRP data in combination with individual-level questionnaire data 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 GRPs to identify statistical relationships between the individual-level questionnaire data and market-level GRPs. Because markets will be randomly assigned to campaign/treatment or control conditions, there is no concern about the randomness of media delivery. With 15 treatment and 15 control markets, there will be a large contrast in potential exposure to the campaign.

We will also use individual measures of exposure to complement market-level exposure data. 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 quitting-related cognitions and 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 may also be more attentive to campaign messages and thus more likely to indicate campaign exposure. However, the smartphone app, which is customized to provide passive campaign exposure, will provide us with the ability to assess this bias by calculating the difference between self-reported

and app-calculated campaign exposure. In other words, the app will be an exogenous measure of individual campaign exposure. 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 using 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 U.S., prevention practitioners, and researchers about the extent of adults' exposure to the point-of-sale campaign's message and the extent to which exposure to this message is associated with changes in targeted 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 point-of-sale campaign among adults in the United States, particularly with estimates of the proportion of the population that was exposed to the campaign.
- Understand the influence of the campaign on beliefs, attitudes, intentions, and behaviors around tobacco use.
- Inform FDA, policy makers, and other stakeholders of the impact of the campaign overall.
- Inform the public about the impact of the campaign.
- Inform future programs that may be designed for similar purposes.
- Inform the feasibility, accuracy, and utility of using geolocation technology to measure mass media campaign exposure.

3. Use of Improved Information Technology and Burden Reduction

This outcome study will rely on a mail-based screener, an in-person field screener, and an in-person evaluation questionnaire for Wave 1. Participants will have the option to complete the Waves 2, 3, and 4 evaluation questionnaires online or in person. In-person data collection increases the accuracy of measurement of key variables of interest. However, online data collection decreases participant allows the participant to complete the questionnaire at their convenience and keeps costs low. Study tablets will be used for field screening. Study laptops will be used for the Wave 1 evaluation questionnaire. Study laptops, participant laptops, or participant tablets will be used to complete the Waves 2-4 evaluation questionnaires. Interviewers will enter responses to the telephone verification surveys into a laptop or tablet computer. Using tablets for field screening provides the benefits of complex case management tools, random selection of one participant per household, and quick, secure electronic transfer of data for in-person screening. Use of tablets and laptops also permits the instrument designer to incorporate questionnaire routings that might be overly complex or not possible with other methods. Interviewer and respondent errors caused by faulty implementation of skip instructions are virtually eliminated. This technology also 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 expense. 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. The self-administered format of the Waves 1, 2, 3, and 4 evaluation questionnaires (using a laptop) and app-based questionnaires (using a smartphone) will increase privacy by allowing participants to input their answers into the computer without the interviewer seeing their responses.

Although the mail screener will not be electronic, FDA estimates that 100% of the respondents will use electronic means to complete the in-person screener, Waves 1, 2, 3, and 4 evaluation questionnaires, the 3 app-based questionnaires, and the 4 telephone verification surveys. Based on burden estimates, an estimated 27,651 mail screeners will be completed on paper, which makes up 36% of all screeners and questionnaires that will be completed as part of the evaluation (77,433) and 25% of the total burden hours.

4. Efforts to Identify Duplication and Use of Similar Information

FDA's point-of-sale campaign efforts are new. To date, there has been no in-depth evaluation of this campaign in a real-world setting, and there are no existing data sources that contain measures on awareness of and exposure to the campaigns for the 15 counties targeted by the campaign. 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 to ascertain that no existing data sets would address the proposed study questions. We have carefully reviewed existing datasets 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 increasing motivation to quit among adult smokers. 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 adults, the National Adult Tobacco Survey, and the Population Assessment of Tobacco and Health. None of these existing data sources meet the data collection needs of the campaign.

5. Impact on Small Businesses or Other Small Entities

Respondents in this study will be members of the general public, 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 questions on an occasional basis. While there are no legal obstacles to reduce burden, any lack of information needed to evaluate the point-of-sale 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 campaign on the lives

of the people it is intended to serve. Failure to collect these data could reduce effective use of FDA’s program resources to benefit adults in the United States. Careful consideration has been given to how frequently the campaign’s intended audience should be surveyed for evaluation purposes. We believe that the proposed mail screener, in-person screener, evaluation questionnaires, and app-based geolocation data collection and brief questionnaires will provide sufficient data to evaluate the campaign 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 evaluation 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 November 15, 2016 (81 FR 80075). Two comments were received, however, only one was PRA-related. The one PRA-related comment claimed that requiring or compelling retailers to display “anti-smoking or anti-tobacco advocacy” is prohibited under the First Amendment. Because the FDA intends to purchase advertising space from retailers on a voluntary basis, the comment raises an issue that is outside the scope of this proposed information 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:

Natalie Gibson
Office of Health Communication and Education
Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-4095
E-mail: natalie.gibson@fda.hhs.gov

Janine Delahanty
Office of Health Communication and Education
Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-9705
E-mail: janine.delahanty@fda.hhs.gov

Chaunetta Jones
Office of Health Communication and Education
Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-0427
E-mail: chaunetta.jones@fda.hhs.gov

Gem Benoza
Office of Health Communication and Education
Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-0088
E-mail: maria.benoza@fda.hhs.gov

April Brubach
Office of Health Communication and Education
Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-796-9214
E-mail: april.brubach@fda.hhs.gov

Katherine Margolis
Office of Science
Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-6766
E-mail: katherine.margolis@fda.hhs.gov

David Portnoy
Office of Science
Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-796-9298
E-mail: david.portnoy@fda.hhs.gov

The following individuals outside of 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.

James Nonnemaker
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-541-7064
E-mail: jnonnemaker@rti.org

Carol Schmitt
RTI International
701 13th Street NW #750
Washington, DC 20005
Phone: 202-728-2046
E-mail: cschmitt@rti.org

Matthew Farrelly
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-541-6852
E-mail: mcf@rti.org

Joseph McMichael
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-485-5519
E-mail: mcmichael@rti.org

Susan Pedrazzani
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-541-6744
E-mail: sdp@rti.org

Thomas Walker
RTI International
701 13th Street NW #750
Washington, DC 20005
Phone: 202-974-7802
E-mail: tomw@rti.org

Christine Carr
RTI International
230 W. Monroe St, Suite 2100
Chicago, IL 60606
Phone: 312-777-5209
E-mail: ccarr@rti.org

Ashley Amaya
RTI International
701 13th Street NW #750
Washington, DC 20005
Phone: 202-728-2486
E-mail: aamaya@rti.org

Melissa Hobbs
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-485-5744
E-mail: mehobbs@rti.org

Leslie Erickson
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-316-3775
E-mail: lerickson@rti.org

Lauren Dutra
RTI International
2150 Shattuck Avenue, Suite 800
Berkeley, CA 94118
Phone: 510-665-8297
E-mail: ldutra@rti.org

Pamela Rao
Akira Technologies, Inc.
1747 Pennsylvania Ave NW Suite 600
Washington, DC 20002
Phone: (202) 517-7187
Email: prao@akira-tech.com

Xiaoquan Zhao
Department of Communication
George Mason University
Robinson Hall A, Room 307B

4400 University Drive, 3D6
Fairfax, VA 22030
Phone: 703-993-4008
E-mail: xzhao3@gmu.edu

Mark Hall
FCB New York
100 West 33rd Street
New York, NY 10001
Phone: 212-885-3372
E-mail: mark.w.hall@fcb.com

Suzanne Santiago
FCB New York
100 West 33rd Street
New York, NY 10001
Phone: 212-885-3651
E-mail: suzanne.santiago@fcb.com

9. Explanation of Any Incentive or Gift to Respondents

Potential participants will be sent a mail screener with a \$2 prepaid cash incentive (\$2 bill). Participants will be offered a \$25 cash incentive for completion of the Wave 1 questionnaire. Participants will be offered a \$25 incentive per wave for the completion of the Waves 2, 3, and 4 outcome evaluation questionnaires, and an additional \$5 for each of the Waves 2, 3, and 4 questionnaires if they complete them online before a specific “early bird” date (in cash for in-person interviews, by check if completed online). This additional \$5 incentive is intended to facilitate timely questionnaires completion and increase the response rate. The cost of the additional incentive is easily offset by reducing the cost of in-person data collection. The early bird incentive was implemented as part of the FDA’s Rural Smokeless Tobacco Evaluation Campaign (RuSTEC) and found to substantially increase response rates (45% of respondents completed the questionnaire online during the early bird period for the first follow-up). Participants will be offered \$5 (delivered as an electronic gift card or as \$5 worth of electronic points that can be redeemed from an online vendor) for completing each of the three brief app-based questionnaires to maintain participation. The gift cards/electronic points delivered after completion of the three app-based surveys are valued at \$15 over the course of the study.

We estimate that the mail screener will take 10 minutes to complete, the in-person screener will take 10 minutes to complete (some, but not all participants will complete both), and that the Waves 1, 2, 3, and 4 questionnaires will take 40 minutes each. We anticipate that each of the three app-based brief questionnaires will take 5 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 11. 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 surveys. The use of incentives will help ensure that data collection is completed in a timely manner and potentially reduce the number of follow-up visits needed to contact nonrespondents. The specific amounts of the proposed incentives (see Table 1) are based on RTI’s previous work on evaluations of FDA’s public education campaigns, including ExPECTT (Evaluation of the FDA’s Public Education Campaign on Teen Tobacco), RuSTEC (Rural Smokeless Tobacco Evaluation Campaign), and EFECT (Evaluation of Fresh Empire Campaign on Tobacco), which found that use of similar incentives increased response rates among youth, particularly for retention in longitudinal studies. Whenever a participant receives an incentive, he or she will sign the Incentive Receipt Form (Attachment 8) for RTI internal recordkeeping purposes.

Table 1. Incentive Type and Amount

| Type of Incentive | Participant | Amount/Value | Total Amount for Completing all Waves |
|--|--|---|---|
| Mail screener | All households identified as containing potential participants in the 30 U.S. counties | \$2 | \$2 |
| App-based questionnaires (3) | All longitudinal panel members who chose to download the app | Electronic points or electronic gift card valued at \$5 | Electronic points or electronic gift card totaling \$15 |
| Wave 1 questionnaire | All longitudinal panel members | \$25 | \$25 |
| Waves 2, 3, and 4 in-person or online questionnaires | All longitudinal panel members | \$25 (plus \$5 “early bird” incentive for online questionnaire completion by a specific date) | \$75-\$90 |

10. Assurance of Privacy Provided to Respondents

In addition to the FDA, RTI's Institutional Review Board (IRB) will review and approve the protocols and consent forms for the outcome evaluation questionnaire and app-based data collection prior to any respondent contact (Attachments 3a, 3b). The IRB's primary concern is protecting respondents' rights, one of which is the privacy of respondent information, which we will maintain 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. The interviewer will introduce the study to potential adult respondents by handing him or her a tablet displaying the Informed Consent Scripts (Attachments 3a, 3b) to read. If respondents have additional questions about the study during or after the informed consent process, the interviewer can field these questions using the Questions and Answers About the Study document (Attachment 7), which includes information on their rights as study participants. Consent will be requested by the interviewer from each respondent. Although full names of respondents and contact information will be collected for all respondents for the purpose of scheduling follow-up appointments, signed consent is waived in this study because only adults will be sampled and no sensitive questions will be asked.

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 use of a laptop for the evaluation questionnaire maximizes privacy by allowing participants to enter their responses directly into the laptop. 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. Participants can refuse to answer any questions except those necessary for determining participant eligibility to participate in the study.

Every 48 hours, interviewers will electronically transmit all completed screening and interview data to RTI's servers via secure encrypted data transmission. In 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 only be used to link questionnaire data and app-based data.

Security for respondents of the app-based geolocation information collection and questionnaires will be assured in a number of ways: (1) All data collected from the app will be stored on secure cloud-based or physical (network) servers and transmitted from the app vendor to RTI via a secure connection; (2) respondents will be provided with information about the protection of the privacy of their data to the fullest extent of the law before they download the app; (3) respondents will be required to provide their

consent before they encounter the first questionnaire item for each of the 3 app-based questionnaires; (4) respondents will have the option to decline to respond to any item in the questionnaire for any reason; (5) respondents will have the option to delete the app from their phone at any time; and (6) all those who handle or analyze data will be required to adhere to the standard data security policies of RTI. Respondents will either use a case identification number or an e-mail address of their choice to log into the app. Participants will be asked to provide an e-mail address to receive incentives for completing the app-based questionnaires. E-mail addresses will be stored on the app developer's secure cloud-based server and RTI's secure server, and all communication of information from the app developer to RTI will be secure. In addition, consent forms state that e-mail addresses will be collected for the app-based portion of the evaluation. E-mail addresses or case identification numbers may be used to link participants' app-based data to their evaluation questionnaire data.

A detailed description of privacy safeguards is provided with this submission (Attachment 12). 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. In addition, all interviewers sign an Interviewer Confidentiality Agreement (Attachment 10) to ensure that they do not share participant responses or any other study information with anyone outside of the research team. 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. 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 questionnaire 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 in 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 laptops in the field, while traveling, and in respondent homes, and protecting the identity of participants.
- All field staff laptops will be equipped with encryption software so that only the field interviewer 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. 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. In addition, the app vendor will have access to participant e-mail addresses. This information will also be stored on secured servers. Only authorized project members and app vendor staff will have access to PII for participants.
- For app-based data collection, the only identifying information that will be logged by the app and stored on the app vendor's server is the e-mail address provided by the participant or the case identification assigned to the participant. Data from the app stored on RTI's secure server will be linked with the participant's e-mail address or case identification number to match app data with in-person questionnaire responses.

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. Respondents will be assured that their answers will not be shared and that their names will not be reported with responses provided. Respondents will be told that the information obtained from all of the questionnaires 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 3a, 3b).

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. 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 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 3a, 3b) will apprise respondents that these topics will be covered during the questionnaire. This study includes a number of procedures and methodological characteristics that will minimize potential negative reactions to these types of questions, including the following:

- Computer-based questionnaires maximize respondent privacy by eliminating 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 study.
- Participants will complete a consent form for the study overall and a specific consent form for the optional app-based portion of the study.
- Participants will have the option to refuse to answer any in-person or app-based questionnaire items (except those necessary for determining eligibility for participation).
- Participants will also have the option to refuse to complete additional interviews or app-based questionnaires and to delete the app at any time.

Finally, as with all information collected, these data resulting from this evaluation will only be presented with all identifiers removed.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the total time reporting burden for this collection to be 18,773 hours. The analogous number in Table 1, 6,258, is the result of dividing by 3 the one-time burden in order to create an annualized estimate. 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 Wave 1 and the Waves 2, 3, and 4 questionnaires (15-20%), we must collect enough interviews at Wave 1 to yield the desired sample sizes at follow-up waves. Based on data from previous longitudinal studies conducted, we estimate that a total of 53,910 screeners (Attachment 1a, 1b) will be completed, 27,651 by mail (9,217 annualized respondents) and 26,258 using the field screener (8,753 annualized respondents). At 10 minutes each, we estimate a total burden of 9,165 hours (3,055 annualized) for the screening process.

An estimated 4,282 adults (1,427 annualized) will complete the consent process (see Attachment 3a) and the Wave 1 evaluation questionnaire (Attachment 2a). Assuming 80% retention between Waves 1 and 2 and 85% retention between Waves 2 and 3, and between Waves 3 and 4, we anticipate 3,426 completes at Wave 2 (1,142 annualized), 2,912 completes at Wave 3 (971 annualized), and 2,475 completes at Wave 4 (825 annualized). The estimated burden per response is 40 minutes for each questionnaire, for a total of 2,869 burden hours for Wave 1 (956 annualized), 2,295 hours for Wave 2 (765 annualized), 1,951 hours for Wave 3 (650 annualized), and 1,658 hours for Wave 4 (553 hours annualized). The Waves 2-4 evaluation questionnaire is provided as Attachment 2b.

We also plan to complete 6,923 (2,308 participants times 3 questionnaires; 2,308 annualized) app-based questionnaires over 18 months (approximately every 6 months) with the same participants who complete the longitudinal evaluation questionnaires. This

figure is based on our assumption that 77% of Wave 1 questionnaire completers will have smartphones (Smith, 2017) and that 70% of those who have smartphones will agree to download the app and complete the 3 app-based questionnaires. At 5 minutes per questionnaire, we estimate a total burden of 554 hours (185 annualized) for the three app-based questionnaires.

In addition to the 4 waves of evaluation questionnaires (over 24 months) and 3 app-based questionnaires (over 18 months), we will also administer a series of five-minute telephone verification questionnaires to a small subsample of participants. Each of the telephone verification questionnaires will occur during the outcome evaluation questionnaire data collection period. This survey is designed to ensure that all study procedures are followed and incentives distributed appropriately (Attachment 13). We anticipate that a random sample of 2,199 participants (733 annualized), and a random sample of 10% of participants who completed the Waves 1 – 4 questionnaires (1,308 individuals [436 annualized]) will complete the telephone verification. At 5 minutes per verification questionnaire, this results in 177 burden hours (59 annualized) for the field screener telephone verifications and 105 burden hours (35 annualized) for the 4 evaluation questionnaire telephone verifications. With participants’ permission, we will perform audio recording of 10% of in-person interviews for quality control. This procedure does not affect burden.

All data collection will take place in 2018, 2019, and 2020. The target number of completed campaign questionnaires for all respondents is 77,433 (25,811 annualized), and the annualized response burden is estimated at 18,772 hours (6,258 annualized). OMB approval is requested for 3 years. Table 2 provides details about how this estimate was calculated.

Table 2.--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 |
|-------------------------------|---|--------------------|---------------------------------|------------------------|-----------------------------|-------------|
| Households (adults 18 and up) | Mail screener | 9,217 | 1 | 9,217 | 0.17 | 1,567 |
| | Field screener | 8,753 | 1 | 8,753 | 0.17 | 1,488 |
| | Telephone verification, field screener | 733 | 1 | 733 | 0.08 | 59 |
| Adult smokers ages 25 to 54 | Wave 1 questionnaire | 1,427 | 1 | 1,427 | 0.67 | 956 |
| | Wave 2 - 4 questionnaires | 2,938 | 1 | 2,938 | 0.67 | 1,968 |
| | Telephone verification, questionnaires 1- 4 | 436 | 1 | 436 | 0.08 | 35 |
| Study participants (opt in) | App-based questionnaire | 769 | 3 | 2,307 | 0.08 | 185 |
| Totals | | | | 25,811 | | 0 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

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 tobacco-related surveys of similar length among adults. We have examined diagnostic data from each of these prior surveys and estimate that data collection for this study will take approximately 40 minutes per respondent. According to the U.S. Department of Labor (DOL) Bureau of Labor Statistics, as of May 2017, the national average hourly wage is \$26.22. Thus, assuming an average hourly wage of \$26.22, the estimated one-year annualized cost to all participants will be \$164,085. The estimated value of respondents’ time for participating in the information collection is summarized in Table 3.

Table 3. Estimated Annual Cost

| Type of Respondent | Activity | Annual Burden Hours | Hourly Wage Rate | Total Cost |
|-------------------------------|---|---------------------|------------------|----------------------------|
| Households (adults 18 and up) | Mail screener | 1,567 | 26.22 | ** Expression is faulty ** |
| | Field screener | 1,488 | 26.22 | ** Expression is faulty ** |
| | Telephone verification, field screener | 59 | 26.22 | ** Expression is faulty ** |
| Adult smokers ages 25 to 54 | Wave 1 questionnaire | 956 | 26.22 | ** Expression is faulty ** |
| | Wave 2 - 4 questionnaires | 1,968 | 26.22 | ** Expression is faulty ** |
| | Telephone verification, questionnaires 1- 4 | 35 | 26.22 | ** Expression is faulty ** |
| Study participants (opt in) | App-based questionnaire | 185 | 26.22 | ** Expression is faulty ** |
| Totals | | 0 | | \$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 are \$9,398,395.90 (Table 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 2018 through 2020.

Table 4. Itemized Cost to the Federal Government

| Government Personnel | Time Commitment | Average Annual Salary | Total |
|-----------------------------|------------------------|------------------------------|----------------|
| GS-13 | 15% | \$107,435 | \$16,115.00 |
| GS-14 | 25% | \$126,958 | \$31,739.00 |
| GS-15 | 5% | \$149,337 | \$7,467.00 |
| | | Total Salary Costs | 0 |
| | | Contract Cost | \$9,343,074.90 |
| | | Total | \$9,398,395.90 |

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 campaign among adult smokers. These estimates will take the form of self-reported ad recognition and recall that assess basic exposure as well as frequency of ad exposure.

Data from this information collection will also be used to examine statistical associations between exposure to and awareness of the campaigns and treatment-control differences in specific outcomes of interest. This will be accomplished with the use of multivariate models that compare measures of each relevant outcome among treatment participants versus control participants, controlling for individual characteristics that may confound the relationship between campaign exposure and differences in outcomes. The primary outcome of interest is quit attempts. We hypothesize that there should be larger differences in outcomes between the control group and individuals in the treatment group who are exposed to the campaigns more frequently or at a higher intensity (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 campaign ads within any given media market. These data will be merged with the data from the outcome evaluation questionnaire 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. Analyses of campaign exposure from the app will supplement this information.

The reporting and dissemination mechanism will consist of three primary components: (1) summary statistics (in the form of PowerPoint presentations and other briefings) on awareness of and reactions to the campaign, (2) comprehensive evaluation reports summarizing findings from this information collection, and (3) manuscript development for 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 Table 5.

OMB approval is requested as soon as possible to begin to recruit, hire, and orient the large study staff that will complete in-person screenings and interviews.

Table 5. Project Schedule

| Project Activity | Date |
|--|---|
| Mail screening | February 2018 to March 2018 |
| Household screening and Wave 1 evaluation questionnaire | March 2018 through June 2018 |
| Telephone verification, field screener and questionnaire 1 | March 2018 through June 2018 |
| App-based questionnaire 1 | August 2018 |
| Wave 2 evaluation questionnaire | October 2018 through January 2019 |
| Telephone verification, questionnaire 2 | October 2018 through January 2019 |
| App-based questionnaire 2 | March 2019 |
| Wave 3 evaluation questionnaire | May 2019 through August 2019 |
| Telephone verification, questionnaire 3 | May 2019 through August 2019 |
| App-based questionnaire 3 | October 2019 |
| Wave 4 evaluation questionnaire | January 2019 through April 2020 |
| Telephone verification, questionnaire 4 | January 2019 through April 2020 |
| 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.