

Information Collection Request

Request for Reinstatement with Change

**Extended Evaluation of the National Tobacco Prevention and Control
Public Education Campaign
OMB Control No. 0920-1083**

Supporting Statement: Part A

Program Official/Contact

Rebecca Murphy, PhD, MPH
Office on Smoking and Health
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
4770 Buford Highway, NE MS F-79
Atlanta, Georgia 30341
OFFICE: 770-488-8964
FAX: 770-488-5939
E-mail: zfg1@cdc.gov

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- **Goal of the Study:** This study will enable Centers for Disease Control and Prevention (CDC) to measure exposure and awareness of the 2017 *Tips From Former Smokers* campaign (The Campaign) and to evaluate its impact on campaign-targeted outcomes among smokers and nonsmokers in the United States. This study is a Reinstatement with minor changes of a longitudinal web-based survey previously approved as OMB No. 0920-1083.
- **Intended use of the resulting data:** These data will be used to evaluate effectiveness of the 2017 Campaign and to help inform the development of the campaign in 2018. Endpoints will include the reach of The Campaign among target audiences and the impact of The Campaign on quit attempts among smokers and other key outcomes.
- **Methods to be used to collect:** Data will be collected via an ongoing longitudinal web-based survey of adult smokers and nonsmokers, recruited from a probability sample of U.S. households. All surveys will be self-administered online.
- **The subpopulation to be studied:** Smokers and nonsmokers in the United States ages 18 years and older.
- **How data will be analyzed:** Descriptive and bivariate analysis will be used to summarize campaign awareness and other key variables collected. Multivariate logistic regressions will be used to estimate outcome variables of interest controlling for other confounding variables measured in the survey.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests OMB approval for a Reinstatement information collection request (ICR) entitled “Extended Evaluation of the National Tobacco Prevention and Control Public Education Campaign”. This work is authorized under the Public Health Service Act (41USC 241) Section 301 (**Attachment A-1**) and the Patient Protection and Affordable Care Act (**Attachment A-3**). Approval is requested for two years in order to assess Phases 6 and 7 of the Campaign.

The evaluation efforts proposed in this information collection are required by the authorizing legislation as follows (**Attachment A-3**): “The Secretary shall ensure that the campaign implemented under paragraph (1) is subject to an independent evaluation every 2 years and shall report every 2 years to Congress on the effectiveness of such campaigns towards meeting science-based metrics.”

In 2012, HHS/CDC launched the National Tobacco Prevention and Control Public Education Campaign (The Campaign). The primary objectives of The Campaign are to encourage smokers to quit smoking and to encourage nonsmokers to communicate with smokers about the dangers of smoking. This campaign, called *Tips From Former Smokers*, aired in 5 phases in 2012, 2013, 2014, 2015, and 2016, respectively. Phases 6 and 7 of The Campaign will be launched in early 2017 and early 2018, respectively. Phase 6 of the campaign will re-use previous ads while Phase 7 will employ newer ads that have not yet aired. However, the 6th and 7th phases will include the same overall message strategies and target audiences, relying on evidence-based paid media advertising that highlights the negative health consequences of smoking. The Campaign’s primary target audience is adult smokers; adult nonsmokers constitute the secondary audience for The Campaign. The Campaign includes paid advertisements aimed at providing motivation and support to smokers to quit, with information and other resources to increase smokers’ chances of success in their attempts to quit smoking. A key objective for the nonsmoker audience is to encourage nonsmokers to communicate with smokers they may know (including family and friends) about the dangers of smoking and to encourage them to quit. The campaign ads also focus on increasing audience’s knowledge of smoking-related diseases, intentions to quit, and other related outcomes. In addition to television advertisements, The Campaign includes complementary ads in radio, Internet, print, outdoor, and other media formats.

The goal of the proposed information collection is to evaluate the reach of The Campaign among intended audiences and to examine the effectiveness of these efforts in impacting specific outcomes that are targeted by Phases 6 and 7 of The Campaign, including quit attempts and intentions to quit among smokers, nonsmokers’ communications about the dangers of smoking, and knowledge of smoking-related diseases among both audiences. This will require customized surveys that will capture all unique messages and components of The Campaign. Information will be collected through Web surveys to be self-administered by adults 18 and over on computers in the respondent’s home or in another convenient location. Evaluating the Campaign’s impact on behavioral outcomes is necessary to determine campaign cost

effectiveness and to allow program planning for the most effective campaign outcomes. Because the campaign content changes with each phase, it is necessary to evaluate each new phase.

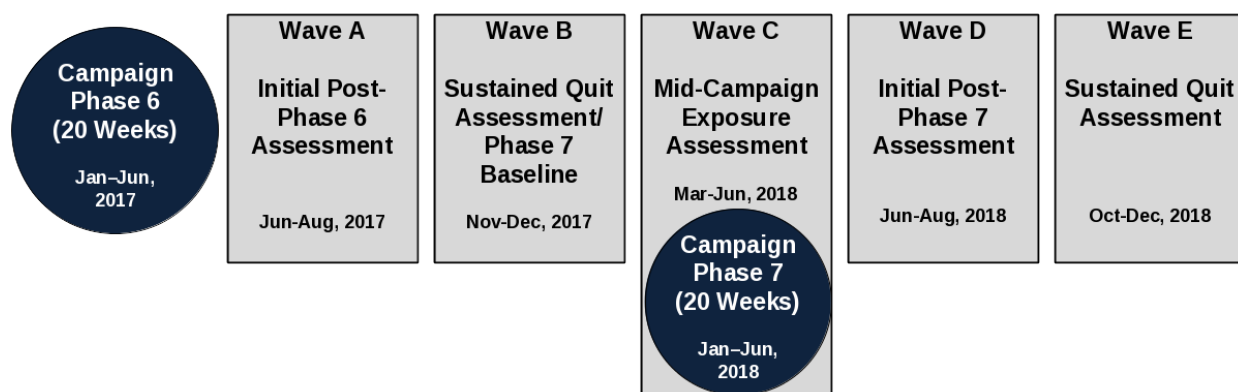
2. Purpose and Use of Information Collection

CDC uses an iterative process of developing new concepts for ads, disseminating them through the campaign, and then evaluating their impact to document their effectiveness as well as to inform future phases of the campaign. Survey items that are no longer needed because of the changes in The Campaign have been eliminated and additional survey items that address new concepts are outlined in Attachment D-2, Changes to Waves A-E Smoker Survey and in Attachment E-2, Changes to Waves A-E Nonsmoker Survey. As a historical perspective, to evaluate The Campaign, CDC obtained OMB approval for information collections beginning in 2012 (OMB No. 0920-0923). Baseline and follow-up surveys were conducted with both smokers and nonsmokers. In 2013, CDC launched Phase 2 of The Campaign and conducted an additional survey with smokers and one additional survey with nonsmokers, also under OMB No. 0920-0923. CDC recently completed collecting the information needed to evaluate Phase 3 of The Campaign, which launched in early 2014. The evaluation of The Campaign in 2014 consisted of a longitudinal cohort using 4 waves of online surveys involving smokers and 3 waves involving nonsmokers to assess their awareness of and reactions to the 2014 advertisements as related to The Campaign's objectives (see previously-approved OMB No. 0920-0923, exp. 3/31/2017). The final wave of this data collection effort also served as a pre-campaign baseline for Phase 4 of the campaign in 2015. The CDC subsequently aired Phase 5 of the campaign in 2016. To evaluate Phases 4 and 5, CDC fielded 4 additional waves of survey data collection. These data collections were fielded from September to November in 2015 and March to June, June to August, and November to December of 2016 (see previously-approved OMB No. 0920-1083, exp. 9/30/2017). Although analyses of these data are ongoing, preliminary results have shown that approximately 75% of the smoker population in the United States was aware of the campaign and there were larger increases in cigarette cessation among those who were exposed to the campaign more frequently.

The final wave of data collected under the currently-approved information collection request (OMB No. 0920-1083, exp. 9/30/2017) will serve as the pre-campaign baseline data for Phase 6. However, additional follow-up waves of survey data are needed in order to fully evaluate these next phases of the campaign in 2017 and 2018. Specifically, additional post-campaign surveys will be needed to measure exposure to and awareness of each campaign among smokers and nonsmokers as well as key campaign-targeted outcomes including quit attempts among smokers, nonsmokers' communications about the dangers of smoking, and knowledge of smoking-related diseases, among others. Data on these measures will be used to analyze the relationship between exposure to the campaign and changes in these key outcomes. These analyses will be conducted with a range of statistical methods including multivariate regressions that will estimate changes in campaign-targeted outcomes as a function of campaign exposure. In addition, we will use results on the campaign's impact on quit attempts and sustained quitting to derive estimates of the campaign's cost effectiveness. Cost effectiveness measurements will be based on calculations of premature deaths averted and life years saved, derived from the total estimated quit attempts and sustained quits attributable to the campaign.

Five waves of information collection will be collected from individual participants in an existing longitudinal web-based panel. See **Figure A.2.1** which illustrates the timing of each data collection relative to Phases 6 and 7 of The Campaign in 2017 and 2018. The participants will be recruited from two sources: (1) an online longitudinal cohort of adult smokers and nonsmokers, sampled randomly from postal mailing addresses in the United States (address-based sample, or ABS); and (2) the existing GfK KnowledgePanel, an established long-term online panel of U.S. adults. The ABS sample will be recruited by GfK, utilizing nearly identical recruitment methods that are used in the recruitment of KnowledgePanel (see **Attachment F**). ABS-sourced participants will make up approximately 65% of the total sample between smokers and nonsmokers (35% will originate from KnowledgePanel). The GfK KnowledgePanel will be used in combination with the ABS-sourced cohort to support larger sample sizes that will allow for more in-depth subgroup analysis, such as racial/ethnic minorities, which is a key objective for CDC. All online surveys, regardless of sample source, will be conducted via the GfK KnowledgePanel Web portal for self-administered surveys.

Figure A.2.1. Proposed Sequence of Information Collection Among Smokers and Nonsmokers Relative to Anticipated Campaign Phases



The first wave (Wave A) of this new data collection will be fielded from approximately August to October 2017 following the conclusion of the Phase 6 campaign (or as soon as possible after receipt of OMB approval). This first wave will serve as an initial post-campaign assessment of Phase 6 ad awareness, campaign exposure, and key outcomes of interest such as quit attempts, intentions to quit smoking, and knowledge of smoking-related diseases. Wave B of this data collection will then be fielded approximately from November 2017 to February 2018 to serve as a 6-month follow-up for purposes of assessing 6-month sustained cigarette cessation. Wave B will also serve as a pre-campaign baseline to Phase 7 of The Campaign which will air in 2018. Wave C will then be conducted while the Phase 7 campaign is on air from approximately March to June 2018. This mid-campaign survey wave will be used to capture short-term changes in key outcomes of interest and to track exposure to the campaign as it is airing, as well as assess 1-year recall of Campaign Phase 6. Wave D will then be fielded approximately from June to August 2018, following the conclusion of the 2018 campaign. This wave will be used to measure full pre-post changes in campaign-related outcomes of interest. Finally, Wave E will be fielded from approximately October to December 2018 to serve as final long-term follow-up for assessing continued sustained cigarette abstinence.

For the practical utility of determining campaign effectiveness, the surveys will include all instrument items that are needed to seamlessly evaluate The Campaign over each of the unique Phases, including audience awareness of and exposure to different Campaign advertisements; knowledge, attitudes, and beliefs related to smoking; and intentions to quit and prior quitting behavior. The surveys will also include measures on nonsmokers' referrals of friends or family who smoke to cessation services and measures of peer communication about the dangers of smoking with friends or family who smoke. In addition, the surveys will include items on other relevant and emerging topics, such as the role of electronic vapor products in the context of dual use and cessation behaviors. The evaluation of The Campaign is conducted in a context that assesses the dynamic nature of tobacco product marketing and uptake of various tobacco products, particularly since these also affect cessation rates. For example, some smokers who attempt to quit may use electronic vapor products as one of their methods. It is important to capture smokers' use of these products to enable us to measure whether or not campaign effects are moderated or mediated by the use of these other products. For these reasons it is also important to measure smokers' exposure to marketing for these products as this may also confound the relationship between exposure to The Campaign and smoking-related behaviors. Therefore, it may be necessary in the future to make additional requests to OMB for changes in the planned instruments to rebalance the content of the surveys to reflect these and other emerging trends in the tobacco product environment.

The screening instrument used for recruiting respondents is located in **Attachment C**, which contains mock screenshots of the screening instrument. The screening tool is only administered for recruiting participants. The Waves A-E questionnaire for smokers is located in **Attachment D-1**, which provides mock screenshots of the smoker survey. We have also provided in **Attachment D-2** an outline of changes that have been made to the currently approved instrument (see OMB No. 0920-1083, exp. 9/30/2017). This attachment includes details on currently-approved wording, revised item wording, and justification for each specific change. These changes have also been transferred to the final Spanish versions of the instruments. The Waves A-E questionnaire for nonsmokers is located in **Attachment E-1**. We have also summarized changes that have been made to the currently approved nonsmoker instrument (see OMB No. 0920-1083, exp. 9/30/2017) in **Attachment E-2**. Final screenshots of the approved instruments will be shared with OMB as soon as the survey is programmed and tested by the data collection staff. Only new ABS participants recruited to replenish the sample are asked the full set of demographics and profile information. Previous participants are not queried on demographics except for things that can potentially change (e.g., education, income, and marital status). Questions to assess demographic characteristics are aligned to mirror the existing GfK KnowledgePanel profile questions so as not to burden participants of this panel with additional questions (e.g., assessment of sexual orientation).

3. Use of Improved Information Technology and Burden Reduction

This information collection will rely on Web surveys to be self-administered to respondents in the GfK Knowledge Panel sample, an established national online panel of adults, and to respondents from a custom-recruited online sample sourced from an address-based sample (ABS). Utilization of these sample sources and Web-based data collection provides a number of

methodological advantages including increased specificity in capturing key variables of interest at the individual level (e.g., patterns of quit attempts, exposure to Campaign, perceived effectiveness of Campaign ads), robust sample characteristics (e.g., stratification of outcomes by racial/ethnic minorities), and reduced burden on study participants since it is automated, electronic, and utilizes other technological collection techniques (e.g., skip patterns). Limitations of this approach include the potential correlation between those with the high smoking rates (lower socioeconomic status, rural areas) and ability to participate in a web-based survey (due either to lack of computer and/or lack of broadband service). Another limitation of this approach is the potential for panel conditioning whereby respondents become more knowledgeable of the survey topics over time. However, this approach yields significant cost efficiencies compared to other modes of data collection such as telephone surveys. These advantages include but are not limited to:

- Convenience and reduced burden to the respondent. Compared to telephone interviewing, Web-based surveys may reduce vulnerability to socially desirable survey responses, particularly on sensitive subjects such as tobacco use. Surveys are self-administered, so the participant may choose a private setting, convenient location, and time, as desired, reducing disruption of their daily activities. Computerized skip patterns also minimize respondent burden by avoiding the presentation of unnecessary questions and information collection based on response logic for survey items.
- Flexible and timely data collection. Because Web surveys do not involve human interviewers and all ensuing requirements for interviewer training and quality control, it is easier and cheaper to launch web surveys very quickly.
- Allows for inclusion of diverse campaign media material including video streaming of campaign ads, streaming of radio ads, and presentation of print materials all within the survey. This significantly enhances the ability to more specifically measure awareness of and exposure to campaign ads. By comparison, telephone surveys do not allow for direct exposure to campaign messages and stimuli. It has been demonstrated that the use of visual cues to prompt ad recognition is a superior method for measuring encoded ad exposure compared to telephonic surveys that must rely on verbal cues from human interviewers to prompt ad recognition (Southwell et al., 2002).

4. Efforts to Identify Duplication and Use of Similar Information

The Campaign encourages smokers to attempt to quit by targeting very specific knowledge, attitudes, and beliefs related to smoking. These specific knowledge and attitudinal constructs are the central components of The Campaigns' messages. Knowledge and attitudinal constructs specific to each campaign are assessed. There are no existing data sources that contain measures on awareness of and exposure to Phases 6 and 7 of The Campaign. Hence, the proposed information collection 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 evaluation questions. Notably, we have coordinated closely with the FDA Center for Tobacco Products, which is responsible for carrying out the Family Smoking Prevention and Tobacco Control Act of 2009 (see **Attachment A-2**). Under this Act, FDA has broad authority

to regulate the manufacturing, distribution, and marketing of tobacco products. We have carefully reviewed a similar data collection activity by FDA (see OMB No. 0910-0753, Evaluation of the FDA's General Market Youth Tobacco Prevention Campaign, exp. 10/31/2016). CDC's campaign is targeted for adults aged 18 – 54 years, whereas FDA's campaign is targeted to youth ages 11 – 16 years at baseline (ages 13 - 18 by the end of the evaluation data collection). Distinct ad campaigns have been developed for the adult and youth audiences. As a result of the specific characteristics of the respondent population for each campaign and each evaluation activity, there is no duplication of effort for the CDC and FDA information collections. However, CDC shared a draft of this information collection plan with the FDA to ensure alignment of question wording on the instruments where topics of mutual interest are included. CDC plans to share its evaluation findings with FDA.

The in-progress Population Assessment of Tobacco and Health (PATH) study (OMB No. 0925-0664) is a large, national, representative longitudinal cohort study of tobacco use and health in the United States sponsored by the FDA which will measure tobacco use behaviors and related health effects. This data collection cannot be modified to be fielded during on and off periods of the campaign, in addition it is not designed to measure awareness and exposure to the Campaign.

We have also reviewed other existing data collection plans by CDC. Other in-progress CDC data collections and existing surveillance systems such as the Behavioral Risk Factor Surveillance System (OMB No. 0920-1061, exp. 3/31/18) would not be able to facilitate the precise timing of evaluation data on The Campaign; are not longitudinal studies; and could not be adequately modified to include the necessary breadth of survey questions on awareness of individual ads and on the outcomes that are important for assessment of the Campaign.

Although Phase 6 of the campaign will re-use older ads, Phase 7 will implement new ads that have not aired previously. Given the government's potential investments in these two campaign phases, it is necessary to document their effectiveness. Therefore, the evaluation of each of these new phases will not represent a duplication of previous efforts.

5. Impact on Small Business or Other Small Entities

Respondents in this study will be members of the general public not business entities. This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

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 CDC's program resources to benefit the health of smokers and nonsmokers in the United States.

Careful consideration has been given to how frequently The Campaign's intended audience should be surveyed for evaluation purposes. Because the proposed information collection consists of a longitudinal cohort, participants will respond up to 5 times with one response per

data collection wave as outlined in **Figure A.2.1**. Responses will occur approximately on a quarterly basis. We believe that the proposed information collection will provide sufficient data to effectively evaluate The Campaign without creating undue burden on respondents.

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

There are no special circumstances that require data collection to be conducted in a manner inconsistent with 5 CFR 1320.5 (d) (2). This request fully complies with the regulation 5CFR1320.5.

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

8.a Federal Register Notice

A 60-day Federal Register Notice was published in the Federal Register on January 5, 2017, vol. 82, No.3, pp.1337-1339 (see Attachment B). CDC did not receive public comments related to this notice.

8.b Consultations

FDA/CTP has received a draft copy of this ICR submission including attachments. Additionally, input has been solicited and received from FDA on the design of this study. The following individuals outside of the agency have been consulted on the audience questionnaire development. CDC/OSH holds regular bi-weekly meetings with FDA's CTP where updates on The Campaign are included as a standing agenda item.

Tesfa N. Alexander, PhD
FDA, Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD 20850
Phone: (301) 796-9335
Email: Tesfa.Alexander@fda.hhs.gov
Year of consultation: 2016

Summary of Unresolved Problems during Consultation: There were no unresolved problems during the consultation.

9. Explanation of Any Payments or Gift to Respondents

Participants recruited to the ABS-sourced sample and who already have internet access in their home will receive \$20 for completion of each survey. ABS-sourced respondents who do not have Internet capability, and must seek out public computers or other types of internet access to complete the online surveys, will receive \$40. The level of incentive for non-Internet households is meant to encourage their participation and appropriately acknowledge their travel and effort in seeking a computer with Internet access. Participants recruited from the existing KnowledgePanel will be offered 15,000 KP bonus points (equivalent to \$15 cash), which are

credited to the KnowledgePanel participant's account and redeemable for merchandise or cash in increments of \$5 or more. This is utilized to maintain consistency of survey response within KnowledgePanel.

The proposed incentive plan represents a continuation of the incentives previously approved under OMB No. 0920-1083. The incentives are intended to convey appreciation for contributing to this important evaluation. Numerous empirical studies have shown that incentives can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999). The decision to use incentives for this study is further justified by the need to ensure high retention from Wave A to Wave E in order to retain the necessary analytic power of the longitudinal study. The higher incentive for respondents in the ABS-sourced longitudinal cohort is needed to encourage participation among individuals who do not have previous long-term experience with online surveys or panels and who may have barriers to participation, such as lack of convenient in-home access to the Internet. The specific amounts of the proposed incentives are the same as those previously approved under OMB No. 0920-1083, exp. 9/30/2017.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

System of Records Under Privacy Act

This submission has been reviewed by CDC's National Center for Chronic Disease Prevention and Health Promotion and CDC's Information System Security Officer who determined that the Privacy Act does not apply. Although identifiable information about respondents will be used to facilitate initial contact and follow-up, the identifying information is maintained in a secure, pre-existing records system owned by GfK Custom Research. The response data transmitted from GfK to RTI International, the data analysis contractor, will be de-identified prior to transmission and analysis. These data will also remain de-identified when transmitted from RTI International to the CDC. All information provided by respondents will be kept private and secure to the extent permitted by law.

No personally identifiable data will be shared with the data analysis contractor (RTI International) or the funding agency (CDC) and therefore will not be reportable (or reported) in any technical reports or publications. Only aggregate respondent data will be shared and disseminated publicly. Therefore, there is no impact of this study on individual respondents' privacy.

The mechanism that will be used for notice or consent is called The Screening & Consent Questionnaire (see **Attachment C**), and will apprise respondents that participation is voluntary and that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer. Participants may opt out of the survey at any time.

The voluntary nature of the information collection is described in the introductory section of the screener questionnaire (**Attachment C**) and the initial invitation letter for ABS-sourced

respondents (**Attachment I-1**) and initial contact email for KnowledgePanel respondents (**Attachment I-2**).

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 evaluation. Please refer to the assurances and study descriptions that are included in the screening instrument (**Attachment C**). 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.

To ensure data security, all RTI and GfK project staff will be required to adhere to strict standards and to sign a non-disclosure 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 to the data restricted to only project staff specifically authorized to work on this project. Survey responses are written in real-time directly to GfK's server and are then stored in a local Oracle database. GfK has developed a secure transmission and collection protocol, including the use of system passwords, encryptions, and firewalls to prevent unauthorized access to the data collection system. Individual identifying information will be maintained separately from completed questionnaires and from computerized data files used for analysis. Individual identifying information is only stored for purposes of administering survey incentives and no respondent identifiers will be contained in data to RTI or reports to CDC and results will only present data in aggregate.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions.

IRB Approval

All procedures have been developed in accordance with federal, state, and local guidelines to ensure that the rights and privacy of participants are protected and maintained. The authorized Institutional Review Board (IRB) of RTI International reviewed and approved all instruments, informed consent materials, and data collection and management procedures (see RTI IRB approval notice in **Attachment G**).

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) or other personal identification numbers. 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., messages about 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 process (**Attachment C**) 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:

- 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 institutional review board Office) to call in case there is a question or concern about the sensitive issue.

Finally, as with all information collected, these data will be presented with all identifiers removed. This safeguard encourages candid responses to questions that may be considered sensitive by a portion of respondents.

12. Estimates of Annualized Burden Hours and Costs

Information will be collected through online surveys involving adult smokers and nonsmokers in the United States, ages 18 years and older. Three survey instruments will be used: a screening & consent questionnaire (see **Attachment C**); a survey for smokers (see **Attachment D-1**); and a survey for nonsmokers (see **Attachment E-1**). Five waves of information collection (Waves A-E) will be collected. Information will be collected in English and Spanish.

We will recruit an estimated 13,000 smokers for Wave A and anticipate that approximately 8,000 (62%) of those will participate in the Wave B follow-up. We anticipate maintaining a total smoker sample size of approximately 8,000 through continued follow-ups and sample replenishment at each of the remaining waves (Waves C, D and E). Approximately 5,000 nonsmokers will be recruited for the Wave A survey and we anticipate that 4,000 (75%) of those will be retained for the Wave B follow-up. A sample of approximately 4,000 nonsmokers will be maintained through continued follow-ups and sample replenishment at each remaining wave (Waves C, D and E) (see **Attachment J**). The estimated follow-up retention and estimated replenishment rates are based on retention rate data from the longitudinal cohort used to evaluate previous phases of The Campaign. Panel attrition determines how much replenishment sample is needed over time versus re-contacts in order to maintain the wave-by-wave targets for sample size. We anticipate that approximately 50,000 individuals will be screened to yield the initial Wave A sample of 13,000 smokers and 5,000 nonsmokers. CDC has examined diagnostic data from previous similar survey projects and estimates that the burden per response is 5 minutes for the screening questionnaire and 30 minutes for the primary survey instrument.

CDC currently plans to field identical instruments in Waves A through E during the period of this evaluation project. However, we recognize that the relevant product market for cigarettes and other forms of tobacco and nicotine and the media environment is very dynamic. It may be necessary to make adjustments to the instrument(s) in these additional three waves that

reflect changes in consumer behavior or the product market. If this occurs, CDC will submit the necessary Change Request(s) to obtain OMB approval of the modified survey instrument(s).

The annual response burden during this period is estimated at 18,585 hours combined for English and Spanish versions of each survey. The total response burden is currently estimated at 37,170 hours over a 2-year clearance period beginning in Fall 2017. Burden hours for each information collection form were calculated by multiplying the total number of responses (equal to number of respondents) by the average burden per response. **Table A.12.1** provides details about how response burden was calculated. The Web self-administered surveys will be designed to maximize ease of response (at home on personal computers) and thus minimize respondent burden.

Table A.12.1. Estimated Annualized Burden Hours

(Type of) Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden (in Hours)
General Population	Screening & Consent Questionnaire (English)	23,750	1	5/60	1,979
	Screening & Consent Questionnaire (Spanish)	1,250	1	5/60	104
Adults Smokers and Nonsmokers, ages 18-54, in the United States	Smoker Survey (Wave A) (English)	6,175	1	30/60	3,088
	Smoker Survey (Wave A) (Spanish)	325	1	30/60	163
	Smoker Survey (Wave B) (English)	3,800	1	30/60	1,900
	Smoker Survey (Wave B) (Spanish)	200	1	30/60	100
	Smoker Survey (Wave C) (English)	3,800	1	30/60	1,900
	Smoker Survey (Wave C) (Spanish)	200	1	30/60	100
	Smoker Survey (Wave D) (English)	3,800	1	30/60	1,900

Smoker Survey (Wave D) (Spanish)	200	1	30/60	100
Smoker Survey (Wave E) (English)	3,800	1	30/60	1,900
Smoker Survey (Wave E) (Spanish)	200	1	30/60	100
Nonsmoker Survey (Wave A) (English)	2,375	1	30/60	1,188
Nonsmoker Survey (Wave A) (Spanish)	125	1	30/60	63
Nonsmoker Survey (Wave B) (English)	1,900	1	30/60	950
Nonsmoker Survey (Wave B) (Spanish)	100	1	30/60	50
Nonsmoker Survey (Wave C) (English)	1,900	1	30/60	950
Nonsmoker Survey (Wave C) (Spanish)	100	1	30/60	50
Nonsmoker Survey (Wave D) (English)	1,900	1	30/60	950
Nonsmoker Survey (Wave D) (Spanish)	100	1	30/60	50
Nonsmoker Survey (Wave E) (English)	1,900	1	30/60	950
Nonsmoker Survey (Wave E) (Spanish)	100	1	30/60	50
Total				18,585

A.12.b Cost Burden to Respondents

Respondents participate on a purely voluntary basis and there are no start-up or maintenance costs. According to the U.S. Department of Labor (DOL) Bureau of Labor Statistics as of June 2016, the national average hourly wage is \$23.35 (DOL, 2016). Thus assuming an average hourly wage of \$23.35, the estimated annualized cost to participants will be \$433,987. The estimated value of respondents' time for participating in the information collection is summarized in **Table A.12.2**.

Table A.12.2. Estimated One-Year Annualized Cost

(Type of) Respondents	Form Name	Number of Respondents	Total Burden Hours	Hourly Wage Rate	Total Cost
General Population	Screening & Consent Questionnaire (English)	23,750	1,980	\$23.35	\$46,233
	Screening & Consent Questionnaire (Spanish)	1,250	104	\$23.35	\$2,428
Adults Smokers and Nonsmokers, ages 18-54, in the United States	Smoker Survey (Wave A) (English)	6,175	3,088	\$23.35	\$72,105
	Smoker Survey (Wave A) (Spanish)	325	163	\$23.35	\$3,806
	Smoker Survey (Wave B) (English)	3,800	1,900	\$23.35	\$44,365
	Smoker Survey (Wave B) (Spanish)	200	100	\$23.35	\$2,335
	Smoker Survey (Wave C) (English)	3,800	1,900	\$23.35	\$44,365
	Smoker Survey (Wave C) (Spanish)	200	100	\$23.35	\$2,335
	Smoker Survey (Wave D) (English)	3,800	1,900	\$23.35	\$44,365
	Smoker Survey (Wave D) (Spanish)	200	100	\$23.35	\$2,335
	Smoker Survey (Wave E) (English)	3,800	1,900	\$23.35	\$44,365
	Smoker Survey (Wave E) (Spanish)	200	100	\$23.35	\$2,335
	Nonsmoker Survey (Wave A) (English)	2,375	1,188-	\$23.35	\$27,740
	Nonsmoker Survey (Wave A) (Spanish)	125	63	\$23.35	\$1,471
	Nonsmoker Survey (Wave B) (English)	1,900	950	\$23.35	\$22,183
	Nonsmoker Survey (Wave B) (Spanish)	100	50	\$23.35	\$1,168

	Nonsmoker Survey (Wave C) (English)	1,900	950	\$23.35	\$22,183
	Nonsmoker Survey (Wave C) (Spanish)	100	50	\$23.35	\$1,168
	Nonsmoker Survey (Wave D) (English)	1,900	950	\$23.35	\$22,183
	Nonsmoker Survey (Wave D) (Spanish)	100	50	\$23.35	\$1,168
	Nonsmoker Survey (Wave E) (English)	1,900	950	\$23.35	\$22,183
	Nonsmoker Survey (Wave E) (Spanish)	100	50	\$23.35	\$1,168
	Total				\$433,987

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

There will be no respondent capital and maintenance costs.

14. Annualized Cost to the Government

This information collection is funded through a contract with RTI International. The total estimated costs attributable to this data collection are approximately \$6,000,000 from June 2017 to December 2018. 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 CDC and its media contractor; evaluation plan development; instrument development; reporting; RTI IRB; and progress reporting and project management. This information collection will occur in 2017 and 2018 over a period of approximately 16-18 months in a clearance period of 2 years. Thus the annualized cost to the Federal government is estimated to be \$3,030,745 (\$3,000,000 RTI cost + \$30,745 CDC cost). Two CDC health communications specialists are responsible for overseeing the content of this information collection, overall project management, and coordination with other CDC activities. The estimated cost of this information collection is summarized in **Table A.14.1**.

Table A.14.1. Itemized Cost to the Federal Government

CDC Staff Member	Annual Salary	% Allocation (Annualized)	Cost (Annualized)
GS-13	\$ 100,081	25%	\$25,020
GS-14	\$114,505	5%	\$5,725
		Subtotal, CDC	\$30,745

		Personnel	
Contractual Costs for Data Collection and Management (RTI)		Subtotal, Contractual Costs	\$3,000,000
		Total Annual Cost	\$3,030,745

15. Explanation for Program Changes or Adjustments

This is a Reinstatement with minor changes of a previously approved information collection. Minor revisions to the survey instruments are enumerated in Attachments D-2 and E-2.

There are increases in the total estimated annualized number of responses and the total estimated annualized burden hours, principally due to the incorporation of one additional wave of follow-up information collection. The previous approval was based on 4 waves of information collection (A-D) and the Reinstatement is based on 5 waves of information collection (Waves A-E). There are no changes to the sample size estimates for Waves A-D. For Wave A, there is an increase of 2 burden hours due to a slight change in the method of calculating (rounding) the total estimated burden hours. The new Wave E is based on estimates for Wave D. These adjustments result in an increase of the total annualized burden hours from 15,584 to 18,585, a net change of approximately 3,000 annualized burden hours. Details are provided in the table below.

Information Collection	Respondents			Burden		
	Previous Approval	Reinstatement Request	Change	Previous Approval	Reinstatement Request	Change
Screening	25,000	23,750 <u>+1,250</u> 25,000	0	2,083	1,979 <u>+104</u> 2,083	0
Wave A Smoker	6,500	6,175 <u>+325</u> 6,500	0	3,250	3,088 <u>+163</u> 3,251	+1 (rounding)
Wave B Smoker	4,000	3,800 <u>+200</u> 4,000	0	2,000	1,900 <u>+100</u> 2,000	0
Wave C	4,000	3,800	0	2,000	1,900	0

Smoker		<u>+200</u> 4,000			<u>+100</u> 2,000	
Wave D Smoker	4,000	<u>+200</u> 3,800 4,000	0	2,000	<u>+100</u> 1,900 2,000	0
Wave E Smoker	0	<u>+200</u> 3,800 4,000	+4,000	0	<u>+100</u> 1,900 2,000	+2,000
Wave A Nonsmoker	2,500	<u>+125</u> 2,375 2,500	0	1,250	<u>+63</u> 1,188 1,251	+1 (rounding)
Wave B Nonsmoker	2,000	<u>+100</u> 1,900 2,000	0	1,000	<u>+50</u> 950 1,000	0
Wave C Nonsmoker	2,000	<u>+100</u> 1,900 2,000	0	1,000	<u>+50</u> 950 1,000	0
Wave D Nonsmoker	2,000	<u>+100</u> 1,900 2,000	0	1,000	<u>+50</u> 950 1,000	0
Wave E Nonsmoker	0	<u>+100</u> 1,900 2,000	+2,000	0	<u>+50</u> 950 1,000	+1,000
Total	52,000	58,000	+6,000	16,583	18,585	+3,002

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 a geographically and demographically varied population of smokers and nonsmokers in the United States. These estimates will take the form of self-reported ad recognition and recall that assess exposure to and 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 Campaign and changes in specific outcomes of interest including the prevalence of quit attempts; consumption of cigarettes and other tobacco and nicotine products among smokers; knowledge, attitudes, and beliefs related to smoking; and nonsmokers' referrals of friends and family who smoke to cessation services. As noted elsewhere in this information collection request, national estimates of changes in these outcomes will be derived from the ABS-sourced samples of smokers and nonsmokers. The combined ABS and KnowledgePanel samples of smokers and nonsmokers will be utilized to generate more detailed estimates of these outcomes

among smaller subgroups of interest, including those by race/ethnicity, income, education, and other characteristics. This is necessary to assess quit behavior patterns and potential aides and barriers to quitting among subgroups. See **Table A.16.1** for an example of how we will present data on exposure to campaign ads by demographic characteristics of smokers and nonsmokers.

Table A.16.1. Example Campaign Ad Awareness Rates, by Demographic Characteristics of Smokers and Nonsmokers

Smoker Subpopulation	Campaign Phase 6 Awareness Rate [95% CI]	Campaign Phase 7 Awareness Rate [95% CI]
Overall (n = X,XXX)	XX.X% [XX.X – XX.X]	XX.X% [XX.X – XX.X]
Ages 18-44 (n = X,XXX)	XX.X% [XX.X – XX.X]	XX.X% [XX.X – XX.X]
Ages 45 and older (n = X,XXX)	XX.X% [XX.X – XX.X]	XX.X% [XX.X – XX.X]
Male (n = X,XXX)	XX.X% [XX.X – XX.X]	XX.X% [XX.X – XX.X]
Female (n = X,XXX)	XX.X% [XX.X – XX.X]	XX.X% [XX.X – XX.X]
White, Non-Hispanic (n = X,XXX)	XX.X% [XX.X – XX.X]	XX.X% [XX.X – XX.X]
Black, Non-Hispanic (n = X,XXX)	XX.X% [XX.X – XX.X]	XX.X% [XX.X – XX.X]
Hispanic (n = X,XXX)	XX.X% [XX.X – XX.X]	XX.X% [XX.X – XX.X]
Other, Non-Hispanic (n = X,XXX)	XX.X% [XX.X – XX.X]	XX.X% [XX.X – XX.X]

Analysis of the relationship between exposure to The Campaign and changes in these outcomes will be accomplished with the use of multivariate models that estimate measures of each relevant outcome as a function of campaign exposure, controlling for individual characteristics that may confound the relationship between the Campaign and changes in outcomes. These models will generally take the form of logistic (or logit) regressions for dichotomous outcomes and ordinary least squares (OLS) regressions for any continuous outcomes that are measured. To account for within-person correlations among respondents who participate in multiple survey waves, all analyses will be clustered on individual IDs using appropriate general estimating procedures. Individual IDs are randomly generated numbers that are used to identify each survey observation.

The primary outcomes of interest among smokers will be awareness of knowledge, attitudes, and beliefs related to smoking; intentions to smoke; making an attempt to quit smoking; and sustained quitting. The primary outcomes of interest among nonsmokers will include communication with friends and family about the dangers of smoking; referrals of friends and family who smoke to cessation services such as telephone quitlines; and the sustained impact of The Campaign on these individuals. We hypothesize that there should be a significant shift in many of these outcomes and longer-term effects in absence of other interventions or policy changes that could also explain such shifts in the outcomes. See **Table A.16.2** for an example of how these results will be presented.

Table A.16.2. Example Model-Based Predictions of Smoking-Related Outcomes [95% CIs]

	Campaign Phase 6		Campaign Phase 7	
	Pre-Campaign	Post-Campaign	Pre-Campaign	Post-Campaign
Incidence of Outcome	XX.X% [XX.X-XX.X]	XX.X% [XX.X-XX.X]	XX.X% [XX.X-XX.X]	XX.X% [XX.X-XX.X]
Odds Ratio for Post-Campaign	X.XX [XX.X – XX.X] (P<X.XX)		X.XX [XX.X – XX.X] (P<X.XX)	
Model N	X,XXX		X,XXX	

To take advantage of the longitudinal nature of these data, we will also examine within-person changes in each outcome over time as a function of within-person changes in Campaign exposure. For example, it will be possible to model changes in quit attempts from Wave A to Wave B as a function of prior Campaign awareness measured at Wave A for the same person. This will enable stronger inferences of The Campaign’s effects based on measures of self-reported exposure to The Campaign.

It should be noted that while the sample recruitment procedures are designed to approximate a nationally representative sample of smokers and nonsmokers, the limitations associated with online data collection require that all results from this information collection be reported with appropriate caution and interpretation. Specifically, although all participants (ABS-sourced and KnowledgePanel-sourced) must be invited to participate and cannot volunteer on their own, there may be systematic differences between individuals who choose to join internet surveys and the type of individuals who do not wish to participate in these types of studies over an ongoing timeframe. Therefore, evaluation results must be interpreted with appropriate caution regarding our ability to generalize the findings to the national population of smokers and nonsmokers.

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. Given the data limitations noted in this ICR, all

interpretation and reporting of evaluation results will be made with reasonable caution and will appropriately acknowledge these limitations. OMB approval is requested by June 2017 or as soon as possible to facilitate an immediate launch of data collection after the conclusion of the Phase 6 campaign which is anticipated to end in June 2017. The project time schedule is summarized in **Table A.16.1**.

Table A.16.1 Project Time Schedule

Project Activity	Time Schedule
Wave A smoker and nonsmoker data collection	1 month within OMB approval
Wave B smoker and nonsmoker data collection	4 – 7 months after OMB approval
Wave C smoker and nonsmoker data collection	8 – 11 months after OMB approval
Wave D smoker and nonsmoker data collection	12 – 14 months after OMB approval
Wave E smoker and nonsmoker data collection	16 – 18 months after OMB approval
Preparation of analytic data file	18 – 22 months after OMB approval
Data analysis	22 months after OMB approval
Report writing and dissemination	22 months after OMB approval

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

The expiration date of OMB approval will be displayed on all information collection instruments.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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