

TIME SENSITIVE

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**Extended Evaluation of the National Tobacco Prevention and Control Public Education Campaign**

Supporting Statement: Part A

Centers for Disease Control and Prevention  
National Center for Chronic Disease Prevention and Health Promotion  
Office of Smoking and Health  
Health Communications Branch

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**HHS/ASPE HAS APPROVED SUBMISSION OF THIS ICR TO OMB**

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THIS INFORMATION COLLECTION REQUEST IS TIME-SENSITIVE

- Goal of the study: This study will enable Centers for Disease Control and Prevention (CDC) to measure exposure and awareness of the 2015 *Tips From Former Smokers* campaign (The Campaign) among smokers and nonsmokers in the United States. This study is an extension of a longitudinal web-based survey under currently-approved ICR 0920-0923.
- Intended use of the resulting data: These data will be used to inform CDC and relevant stakeholders about the effectiveness of the 2015 Campaign and to help inform the evaluation of the campaign in 2016. This will include providing data on the reach of The Campaign among its target audiences and the impact of The Campaign on quit attempts among smokers and other key outcomes.
- Methods to be used to collect data: Data will be collected via an ongoing longitudinal web-based survey of 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.

OMB APPROVAL IS REQUESTED AS SOON AS POSSIBLE

## Overview

In 2012, HHS/CDC launched Phase 1 of 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. 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 Information Collection Request (ICR) 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 consists 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 currently-approved ICR 0920-0923, exp. 3/31/2017).

Phase 4 of The Campaign was implemented on March 30, 2015 and ended on August 16, 2015. The third wave of data collected to evaluate Phase 3 of the campaign immediately preceded the implementation of the Phase 4 (data collected January 5<sup>th</sup> to March 16<sup>th</sup> 2015). These data will serve as a pre-campaign baseline for Phase 4. CDC proposes to field 4 new waves of survey data collection to fully evaluate Phase 4 of The Campaign. The first wave (Wave A) is planned to launch in September 2015 following the conclusion of the Phase 4 campaign. This first wave will serve as an initial post-campaign assessment of Phase 4 ad awareness, campaign exposure, and key outcomes of interest. Wave B of this data collection will then be fielded approximately from March to June 2016 to serve as a 6-month follow-up for purposes of assessing 6-month sustained cigarette cessation. Wave C will be conducted approximately from July to September 2016 and Wave D will be fielded approximately from October to December 2016 to serve as final long-term follow-ups for assessing continued sustained cigarette abstinence. These data collection will also help to inform the evaluation of Phase 5 of The Campaign.

This data collection will continue to utilize the longitudinal cohort implemented to evaluate Phase 3 of The Campaign in 2014. Each data collection wave will consist of separate surveys of smokers and nonsmokers since The Campaign targets specific outcomes among each of these populations. These data collections are necessary for measuring awareness of The 2015 Campaign (Phase 4) and related outcomes among its target audience as well as informing the evaluation of The 2016 Campaign.

OMB approval is requested for two years.

### A. Justification

## **A.1. Circumstances Making the Collection of Information Necessary**

The primary mission of the Health Communications Branch (HCB) of the Office on Smoking and Health (OSH) at the Centers for Disease Control and Prevention (CDC) is to serve as a public health resource for tobacco and health information. Through the HCB, OSH 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. OSH also maintains a reference library of tobacco-related communication materials, called the Media Campaign Resource Center (MCRC), which contains CDC-licensed advertisements developed by state health departments, nonprofit organizations, and the federal government. CDC is authorized to conduct information collection supporting these activities under the Public Health Service Act (41USC 241) Section 301 (**Attachment A-1**). OSH also collaborates closely with the Center for Tobacco Products (CTP) in the Food and Drug Administration (FDA) and other federal agencies on tobacco control. Since 2009, the FDA has gained broad authority to regulate tobacco product advertising through the Family Smoking Prevention and Tobacco Control Act (**Attachment A-2**).

The recent enactment of the Affordable Care Act (ACA) established the Prevention and Public Health Fund (PPHF) which contains essential disease prevention initiatives to help reduce the health and financial burden of tobacco use (**Attachment A-3**). One of these major initiatives includes the implementation of a national, evidence-based media campaign to increase awareness of the health consequences of tobacco use and exposure to secondhand smoke. This campaign, called *Tips From Former Smokers*, aired in 4 phases in 2012, 2013, 2014, and 2015 respectively. Evaluation of the fourth phase in 2015 is the focus of this information collection request. Similar to the previous phases, the fourth phase which aired from March to August 2015 includes evidence-based paid media advertising that highlights the negative health consequences of smoking. The Campaign's primary target audience is adult smokers. 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. Thus, the primary objective of The Campaign is to encourage smokers to attempt to quit smoking. A secondary audience for The Campaign is adult nonsmokers. 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. In addition to television advertisements that aired nationally in 2015, The Campaign included 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 cognitive and behavioral outcomes that are targeted by Phase 4 of The Campaign. This will require customized surveys that will capture all unique messages and components of The Campaign. For example, The Campaign's messages will focus on specific

health conditions that are caused by smoking, such as chronic obstructive pulmonary disease, macular degeneration, and colorectal cancer. Hence, it is critical that we measure smokers' and nonsmokers' knowledge of these conditions and other key messages that are featured in Campaign ads.

#### Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

All participants will be 18 years of age or older. The Campaign Website does not have content directed to children younger than age 13. In addition, the Web-based surveys will only be accessible to participants of the study.

### **A.2. Purposes and Use of Information Collection**

#### Overview of the Information Collection Systems

Evaluation results from Phases 1, 2, and 3 of The Campaign have primarily been used to inform the development and implementation of Phase 4 of The Campaign. Results for the evaluation of Phase 1 of The Campaign indicate that the campaign had high levels of awareness among smokers and nonsmokers and was effective at increasing population-level quit attempts; quit attempt rates increased the most among African Americans (McAfee et al, 2013). In addition, this national, federally funded mass media antismoking campaign can be extremely cost-effective to reduce the burden of tobacco use. Phase 1 of the Campaign is estimated to have saved an estimated 179,099 quality-adjusted life years (QALYs) and prevented 17,109 premature deaths in the United States (Xu et al, 2015). With a campaign cost of roughly \$48 million, The Campaign spent approximately \$480 per quitter, \$2,819 per premature death averted, \$393 per life-years saved and \$268 per QALY gained. Additional evaluation results for Phase 2 of The Campaign have been shared with HHS, CDC, and FDA officials and other stakeholders to inform planned health communication efforts within the Department. Phase 3 data collection was completed in June 2015 and analyses are ongoing.

Four waves of information collection will be collected from individual participants in an existing longitudinal web-based panel . 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.

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 RTI Institutional Review Board (IRB) reviewed and approved all instruments, informed consent materials, and data collection and management procedures (see RTI IRB approval notice in **Attachment G**).

#### Items of Information to be Collected

The surveys will include all instrument items that are needed to continuously evaluate The Campaign over all Phases, including audience awareness of and exposure to 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 that smoke to cessation services and measures of peer communication about the dangers of smoking with friends or family who smoke. For the evaluation of Phase 4 of the Campaign, questions were also added to in relation to new aspects of the campaign (e.g., new health conditions, digital ad placement); questions primarily relevant to prior campaigns were removed as to not increase burden hours. In addition, the surveys will include additional survey 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 successful cessation rates. 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**. The screening tool is only administered for recruiting participants. The Waves A-D questionnaire for smokers is located in **Attachment D**. The Waves A-D questionnaire for nonsmokers is located in **Attachment E**. 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).

#### Methods and Purposes of Sharing the Information to be Collected

The information obtained from the proposed data collection activities will be used to inform CDC, policy makers, adult smokers and nonsmokers in the United States, prevention practitioners, and researchers about the extent of adults' exposure to The Campaign's messages nationally and the extent to which exposure to these messages is associated with

changes in outcomes targeted by The Campaign. Primary and secondary outcomes that will be estimated for this evaluation are discussed in detail in Section A.16. While not exhaustive, the list below illustrates a range of purposes and uses for the proposed information collection:

- Provide data on the reach of The Campaign among adults in the United States, particularly with estimates of the proportion of the population and subgroups that were exposed to The Campaign.
- Understand the potential influence of The Campaign on attitudes, knowledge, beliefs, and behaviors around tobacco use and smoking cessation behaviors.
- Understand the potential influence of The Campaign on short-term (3-month) and long-term (6 to 12-month) quit success and cigarette abstinence among smokers who attempt to quit as a result of exposure to The Campaign.
- Understand how emerging patterns in tobacco and nicotine product consumption, including smokers' use of electronic vapor products may influence the impact of The Campaign on the quitting process.
- Provide data on the cost effectiveness of resources invested in The Campaign's development and implementation. Inform the health communication efforts related to the release of the Reports of the Surgeon General. For example, this information will generate a better understanding of The Campaign's impact on key precursors to smoking cessation such as self-efficacy to quit.
- Inform the health communication efforts undertaken by the FDA including upcoming campaigns that while intended for different audiences can benefit from knowledge of the approaches utilized for this study.

All communications about the evaluation results via these uses of the information, including any and all Congressional testimony, will carefully enumerate and describe any underlying limitations of the data and ensure that evaluation results are interpreted with appropriate care and caution. Specifically, we believe this evaluation design allows CDC to estimate the potential for this type of campaign to reach a national population, to gauge change in knowledge and behaviors of smokers and nonsmokers, and to generate hypotheses about potential differences in responsiveness by subgroups of interest. This design represents a reasonable approach to CDC's evaluation objectives, within the time, cost, and feasibility constraints noted above.

No respondent identifiers will be contained in data to RTI or reports to CDC and results will only present data in aggregate. Results will be disseminated to CDC project leaders and staff in the form of technical reports and presentations. Aggregate results may also be shared publicly via peer-reviewed articles in scientific journals.

### **A.3. Use of Improved Information Technology and Burden Reduction**

Data will be collected from the existing longitudinal cohort implemented to previously evaluate Phase 3 of The Campaign (see currently-approved ICR 0920-0923, exp. 3/31/2017). This study 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 (for Phase 3) 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. On the other hand, limitations 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). 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. 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.
- 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 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).

#### **A.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 (e.g. the addition of questions assessing awareness that smoking is related to macular degeneration, a condition highlighted in Phase 4 of The Campaign). There are no existing data sources that contain measures on awareness of and exposure to The Campaign or the many specific knowledge and attitudinal constructs that

are highlighted by 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. We have carefully reviewed existing data collection plans by other agencies such as FDA that are conducting similar data collection activities (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 to adults ages 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 and other appropriate HHS agencies.

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. Other in-progress 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.

The HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) has reviewed this proposed collection of information and approved its submission to OMB for further consideration.

#### **A.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.

#### **A.6. Consequences of Collecting the Information Less Frequently**

The evaluation efforts proposed in this study 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.” While there are no legal obstacles to reduce burden, any lack of information needed to evaluate The 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 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. We believe that the proposed longitudinal study will provide sufficient data to effectively evaluate The Campaign without creating undue burden on respondents.

#### **A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

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

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

##### *A.8.a. Federal Register Notice*

A 60-day Notice was published in the *Federal Register* on February 25, 2015, Volume 80, No. 37, pages 10095-10096 (**Attachment B**). No public comments were received.

##### *A.8.b. Consultation*

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. 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.

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#### **A.9. Explanations of Any Payment or Gift to Respondents**

Participants recruited to the ABS-sourced sample will be offered \$20 for completion of each survey in which they participate. As demonstrated in Section A12 Exhibit1A, differential incentives are requested for the ABS-sourced sample as there is no long-standing history of survey participation or panel relationship with those respondents. These incentive structures are customary for initial empanelment of the ABS-sourced cohort; this incentive would represent a continuation of incentive approved under currently-approved ICR 0920-0923. An incentive of \$40 will be offered to 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. This additional incentive for non-Internet households is meant to encourage their participation and appropriately acknowledge their time and effort in seeking a computer with Internet access. Offering this incentive is a more cost-efficient way of including lower-income, non-Internet households in the survey compared to GfK's usual protocol of providing free netbook laptops and Internet access to non-Internet households. Providing laptops and Internet access to non-Internet households is prohibitively expensive to this project and thus we are offering the additional incentive as a lower-cost alternative to encourage participation of non-Internet households. 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 the standard incentive amount for KnowledgePanel surveys and is utilized to maintain consistency of survey response within KnowledgePanel..

The incentives are intended to recognize the time burden placed on participants, encourage their cooperation, and to convey appreciation for contributing to this important evaluation and are similar to incentives that are offered for most surveys among participants in

panel-based Web surveys. 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 on the need to ensure high retention from Wave A to Wave D in order to retain the necessary analytic power of the longitudinal study. The higher payment to respondents in the ABS-sourced longitudinal cohort is needed to encourage participation among individuals who do not have previous 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 based on several previous projects conducted by RTI and GfK Custom Research, which found that use of similar incentives increased response rates among adults, particularly for retention in longitudinal studies.

## **A.10. Assurance of Confidentiality Provided to Respondents**

### **A.10.1 Privacy Impact Assessment Information**

#### Impact on Respondents' Privacy

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.

#### Informing Respondents' that Participation is Voluntary

The Screening & Consent Questionnaire (see **Attachment C**) 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.

#### Opportunities to Consent to Sharing Information Collected

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.

### Securing the Information and Data Collected

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.

### 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 Collection Review Office, which have 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.

#### **A.11. Justification for Sensitive Questions**

The majority of questions asked will not be of a sensitive nature. There will be no requests for a respondent's Social Security Number (SSN). However, it will be necessary to ask some questions that may be considered to be of a sensitive nature in order to assess specific health behaviors, such as cigarette smoking. These questions are essential to the objectives of this information collection. Questions about messages concerning lifestyle (e.g., 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 IRB 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.

## **A.12. Estimated Annualized Burden Hours and Cost**

### **A.12.a. Estimated Annualized Burden to Respondents**

Information will be collected through online surveys involving adult smokers and nonsmokers in the United States, ages 18-54 years. Three survey instruments will be used: a screening & consent questionnaire (see **Attachment C**); a survey for smokers (see **Attachment D**); and a survey for nonsmokers (see **Attachment E**). Four waves of information collection (Waves A-D) will be collected. Information will be collected in English and Spanish. OMB approval is requested for 2 years.

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 and D). 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 and D) (see **Attachment J**). The estimated follow-up retention and estimated replenishment rates are based on data from the longitudinal cohort used to evaluate Phase 3 of The Campaign provided in **Exhibit 1A**. Panel attrition allows estimation of how much replenishment sample is needed over time versus re-contacts in order to maintain that wave-by-wave targets for sample size .

The annualized targets are provided in **Exhibit 1B**. 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's data collection contractor 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 D during the

period of this evaluation project. However, we recognize that the relevant product market 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 total response burden is currently estimated at 31,168 hours over a 2-year clearance period between September 2015 and December 2016. The annual response burden during this period is thus estimated at 15,584 hours. **Exhibit 1B** 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.

#### Exhibit 1A. Historical Cohort Participation Patterns

	Smokers		Nonsmokers	
	KP	ABS	KP	ABS
<b>Wave 1</b>	----	----	----	----
<b>Waves 1 &amp; 2</b>	80.2%	65.6%	79.9%	67.6%
<b>Waves 1, 2, &amp; 3</b>	87.8%	71.0%	81.7%	75.2%
<b>Waves 1, 2, 3, &amp; 4</b>	70.3%	76.3%	----	----
<b>Wave 1 - 2 Total Retention</b>	80.2%	65.6%	79.9%	67.6%
<b>Wave 1 - 3 Total Retention</b>	70.4%	46.6%	65.2%	50.9%
<b>Wave 1 - 4 Total Retention</b>	49.5%	35.5%	----	----

#### Exhibit 1B. Estimated Annualized Burden Hours

Type of Respondent	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	25,000	1	5/60	2,084
Adults Smokers	Smoker Survey (Wave A)	6,500	1	30/60	3,250

and Nonsmokers , ages 18-54, in the United States	Smoker Survey (Wave B)	4,000	1	30/60	2,000
	Smoker Survey (Wave C)	4,000	1	30/60	2,000
	Smoker Survey (Wave D)	4,000	1	30/60	2,000
	Nonsmoker Survey (Wave A)	2,500	1	30/60	1,250
	Nonsmoker Survey (Wave B)	2,000	1	30/60	1,000
	Nonsmoker Survey (Wave C)	2,000	1	30/60	1,000
	Nonsmoker Survey (Wave D)	2,000	1	30/60	1,000
Total					15,584

**A.12.b. Estimated Annualized Burden Costs**

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 March 2011, the national average hourly wage is \$22.89. Thus assuming an average hourly wage of \$22.89, the estimated annualized cost to participants will be \$356,718. The estimated value of respondents' time for participating in the information collection is summarized in **Exhibit 2**.

**Exhibit 2. Estimated One-Year Annualized Cost**

Type of Respondent	Form Name	Number of Respondents	Total Burden Hours	Hourly Wage Rate	Total Cost
General Population	Screening and Consent Questionnaire	25,000	2,084	\$22.89	\$47,703
Adults Smokers and Nonsmokers , ages 18-54, in the United States	Smoker Survey (Wave A)	6,500	3,250	\$22.89	\$74,393
	Smoker Survey (Wave B)	4,000	2,000	\$22.89	\$45,780
	Smoker Survey (Wave C)	4,000	2,000	\$22.89	\$45,780
	Smoker Survey (Wave D)	4,000	2,000	\$22.89	\$45,780
	Nonsmoker Survey (Wave A)	2,500	1,250	\$22.89	\$28,613

	Nonsmoker Survey (Wave B)	2,000	1,000	\$22.89	\$22,890
	Nonsmoker Survey (Wave C)	2,000	1,000	\$22.89	\$22,890
	Nonsmoker Survey (Wave D)	2,000	1,000	\$22.89	\$22,890
	Total				\$356,718

**A.13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers**

None.

**A.14. Estimates of Annualized Cost to the Federal 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 September 2015 to December 2016. 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 2015 and 2016 over a period of approximately 16 months in a clearance period of 2 years. Thus the annual cost to the Federal government is estimated to be \$3,023,881 (\$3,000,000 RTI cost + \$23,881 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.

Itemized Cost to the Federal Government			
CDC Staff Member	Annual Salary	% Allocation (Annualized)	Cost (Annualized)
GS-12	\$72,620	25%	\$18,155
GS-14	\$114,505	5%	\$5,726
		<b>Subtotal, CDC Personnel</b>	<b>\$23,881</b>
<b>Contractual Costs for Data Collection and Management (RTI)</b>		<b>Subtotal, Contractual Costs</b>	<b>\$3,000,000</b>

		Total	\$3,023,881
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**A.15. Explanation for Program Changes or Adjustments**

None. This is a new information collection request.

**A.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.

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. 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.

Cost-effectiveness analysis was conducted in 2013 to evaluate Phase 1 of the campaign from a funding agency's perspective. Estimates of sustained cessations; premature deaths averted; undiscounted life years (LYs) saved; and quality-adjusted life years (QALYs) gained by Tips were estimated (Xin references). Results demonstrated that with a campaign cost of roughly \$48 million, The Campaign spent approximately \$480 per quitter, \$2,819 per premature death averted, \$393 per life-years saved and \$268 per QALY gained. Subsequent phases of The Campaign will continue to be evaluated on the return on investment for implementation on reducing mortality and morbidity related to tobacco use.

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 these data limitations, all interpretation and reporting of evaluation results will be made with reasonable caution and will appropriately acknowledge these limitations. The key events and reports to be prepared are listed in **Exhibit 3**.

Phase 4 of The Campaign began on March 30, 2015 and ended on August 16, 2015. OMB approval is requested by as soon as possible.

### **Exhibit 3. Project Schedule (estimated)**

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<b>Project Activity</b>	<b>Date</b>
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Wave A smoker and nonsmoker data collection	September-October 2015
Wave B smoker and nonsmoker data collection	March—June 2016
Wave C smoker and nonsmoker data collection	July 2016–September 2016
Wave D smoker and nonsmoker data collection	October–December 2016
Preparation of analytic data file	2-4 weeks after completion of data collection
Data analysis	Ongoing beginning 2 weeks after Wave A completion
Report writing and dissemination	Ongoing during data collection

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**A.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.

**A.18. Exceptions to the Certification Statement**

Not applicable. No exceptions to the certification statement are being sought.

## References

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