

TIME SENSITIVE

**Evaluation of the CDC National Tobacco Prevention and Control Public Education Campaign
(OMB No. 0920-0923, exp. 4/30/2014)**

Revision

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
OMB APPROVAL IS REQUESTED BY March 1, 2014, OR AS SOON AS POSSIBLE

Phase 3 of CDC's national tobacco prevention and control public education campaign, commonly known as the "Tips from Former Smokers" campaign is expected to launch in early 2014 and to air for approximately 8-9 weeks, followed by a second 8-9 week airing in late summer 2014. Due to pending decisions on the paid media buy, some specifics of campaign launch and duration have not been finalized as of the date of submission of this information collection request.

The campaign evaluation is based on repeated measures of outcomes of interest, including awareness of and exposure to the campaign, quit attempts, and cognitive and behavioral indicators related to quitting. In order to accurately assess the effectiveness of the campaign, information collection must be initiated near the campaign launch date.

The current estimated campaign launch date is February 1, 2014. OMB approval is requested by March 1, 2014, or as soon as possible.

Overview

In 2012, HHS/CDC launched Phase 1 of the National Tobacco Education Campaign. The primary objectives of the campaign are to encourage smokers to quit smoking and to encourage non-smokers to communicate with smokers about the dangers of smoking. To evaluate the campaign, CDC obtained OMB approval for two information collections in 2012 (OMB No. 0920-0923, exp. 2/28/2013). Baseline and follow-up surveys were conducted with both smokers and non-smokers.

In 2013, CDC launched Phase 2 of the campaign and conducted one additional survey with smokers and one additional survey with non-smokers (OMB No. 0920-0923, exp. 4/30/2014).

CDC also plans to collect the information needed to evaluate Phase 3 of the campaign, which is scheduled to launch in early 2014. As with previous phases, CDC proposes to conduct a series of Web-based surveys involving both smokers and non-smokers. The Phase 3 evaluation will involve more extended follow-up on a smaller group of respondents. The information collection will allow CDC to assess campaign reach and to examine the statistical relationships between exposure to the campaign and changes in outcomes that are targeted by the campaign. CDC is specifically interested in longer-term cigarette abstinence among smokers who initially report quitting as a result of the campaign and their exposure to alternative products, including electronic cigarettes. The Phase 3 evaluation plan is designed to address this gap in knowledge.

This Revision request describes the following changes for the Phase 3 evaluation:

1. Data collection will be based on a longitudinal study design to facilitate analysis of repeated measures of outcomes of interest. Five (5) waves of data collection will be conducted with smokers, and four (4) waves of data collection will be conducted with non-smokers.
2. There is a net decrease in the annualized number of responses with a small net increase in total annualized burden hours.
3. The survey instruments will be modified to capture information about unique messages and components of the Phase 3 campaign, such as the health conditions that are caused by smoking. The surveys will also measure behaviors related to smoking cessation (among the smokers in the sample) and behaviors related to non-smokers' encouragement of smokers to quit smoking, recommendations of cessation services, and attitudes about other tobacco and nicotine products. In addition to collecting information on outcomes that are specifically related to The Campaign's messages, the surveys will also include measures on many individual characteristics that will be used as control variables in the analyses.
4. The estimated burden per response will increase from 25 minutes to 30 minutes.

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), and provides technical assistance to organizations so that MCRC materials can be customized for specific media applications. 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 2 phases in 2012 and 2013, and a third phase is planned for 2014. Evaluation of this third phase in 2014-2015 is the focus of this information collection request. The third phase is currently under development and will include evidence-based paid media advertising that highlights the negative health consequences of smoking. The Campaign's primary target audience is adult smokers. The Campaign will include 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 non-smokers. A key objective for the non-smoker audience is to encourage non-smokers to communicate with other 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 will air nationally in 2014, The Campaign will include 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 3 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, including tracheotomies, heart disease, and Buerger's disease. Hence, it is critical that we measure smokers' and nonsmokers knowledge of these conditions and other key messages that are featured in Campaign ads. **Attachment C-6** provides a summary of key changes in the evaluation constructs for Phase 1, Phase 2, and Phase 3 of the Campaign.

Privacy Impact Assessment

Overview of the Information Collection

This study will rely on Web surveys to be self-administered on computers at home or in a location convenient to the respondent. The surveys will be fielded in English and Spanish. Specifically, we will conduct a multi-wave longitudinal study of smokers (5 waves) and non-smokers (4 waves) to facilitate repeated measures on outcomes related to the evaluation. The first survey will be fielded from March to June in 2014. Variables of interest to the evaluation include knowledge, attitudes, and beliefs related to smoking as well as intentions to quit and prior quitting behavior. The survey 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. Participants who complete the wave 1 survey will be surveyed again in a follow-up survey approximately 3 months later. This timeframe for follow-up data collection correlates with the duration of The Campaign itself. This will facilitate analysis of relationships between individuals' exposure to The Campaign and changes in outcomes of interest. Subsequent follow-up surveys (3 for smokers, 2 for nonsmokers) will occur on a quarterly basis after the first two surveys are completed. One of the primary purposes of the subsequent follow-up surveys will be to track longer-term cigarette abstinence among smokers who initially report quitting as a result of The Campaign. This will be essential to properly estimating the impact of The Campaign on long-term successful quitting. In addition, follow-up surveys may include additional survey items on other relevant topics, including cigars, noncombustible tobacco products, and other emerging trends in tobacco use. It is important to evaluate The Campaign 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 follow-up instruments to rebalance the content of the surveys to reflect these and other emerging trends in the tobacco product environment.

The participants for these surveys will be recruited from two sources: (1) a new online longitudinal cohort of adult smokers and nonsmokers, sampled randomly from postal mailing addresses in the U.S. (address-based sample (ABS) cohort); and (2) the existing GfK KnowledgePanel, an established long-term online panel of U.S. adults. The new ABS-sourced longitudinal cohort will consist of smokers and nonsmokers who have not previously participated in any established online panels. This will serve as the core sample upon which

estimates of key outcomes will be made. The use of a newly-recruited ABS-sourced sample addresses will increase the national representativeness of the core sample and will alleviate possible concerns over ‘panel conditioning’ and other limitations of existing online panels. This new cohort will be recruited by GfK, utilizing nearly identical recruitment methods that are used in the recruitment of KnowledgePanel. The GfK KnowledgePanel will be used in combination with the new ABS-sourced cohort to support larger sample sizes that will allow for more in-depth subgroup analysis, which is a key objective of the CDC. All online surveys, regardless of sample source, will be conducted via the GfK KnowledgePanel Web portal for self-administered surveys.

CDC has taken into account an array of considerations in determining this approach, including the need for rapid data collection, cost efficiency, and accurate data. CDC has further consulted with colleagues at CTP/FDA and with leading academic experts in media evaluation and has determined this approach to be consistent with the current state of the art in media evaluation methodology and will be acceptable in the peer review process. Consequently, we believe this approach provides the best available solution to CDC’s evaluation objectives, within the time, cost, and feasibility constraints noted above.

Items of Information to be Collected

Each survey will include measures on knowledge, attitudes, and beliefs related to smoking and secondhand smoke, as well as behaviors related to smoking cessation (among the smokers in the sample) and peer-to-peer communication about smoking. Each survey will include measures of audience awareness of and exposure to The Campaign advertisements as well as follow-up measures on the aforementioned outcome variables of interest. The screening instrument used for recruiting respondents is located in **Attachment C-1**. The wave 1 and follow-up questionnaires (waves 2-5) for smokers are located in **Attachments C-2 and C-3**. The wave 1 and follow-up questionnaires (waves 2-4) for non-smokers are located in **Attachments C-4 and C-5**. As noted above, the content the follow-up questionnaires may need to be rebalanced at a later date to better assess the influence of emerging trends and patterns of quitting, requiring us to submit requests for changes to OMB when necessary.

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

Phase 1 evaluation results have primarily been used to inform the development and implementation of the Phase 3 campaign. At the time of planning and development of the Phase 2 campaign, Phase 1 evaluation analyses were still underway. Results however, have been shared with HHS, CDC, and FDA officials and other stakeholders to inform planned health communication efforts within the Department. Phase 2 data collection ended this past September and initial analyses are forthcoming.

The information obtained from the proposed data collection activities will be used to inform CDC, policy makers, adult smokers and non-smokers in the U.S., 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 U.S., particularly with estimates of the proportion of the population and subgroups that were exposed to The Campaign.
- Understand the influence of The Campaign on attitudes, knowledge, beliefs, and behaviors around tobacco use and smoking cessation behaviors.
- Understand the influence of The Campaign on long-term quit success and cigarette abstinence among smokers who attempt to quit as a result of exposure to The Campaign.
- Inform CDC, policy makers, and other stakeholders on the impact of The Campaign overall.
- Inform CDC, policy makers, and other stakeholders on patterns in tobacco and nicotine product consumption including smokers' use of electronic cigarettes and how use of other tobacco products may impact the quitting process.
- Inform the public through scientific reports, publications, and conference presentations about the impact of The Campaign and cost effectiveness of resources invested in The Campaign's development and implementation.
- Inform the health communication efforts related to the release of Surgeon General reports. 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 Food and Drug Administration including upcoming campaigns that while intended for different audiences can benefit from knowledge of the approaches utilized for this study.
- Inform future programs that may be designed for similar purposes to ensure the most cost-effective use of funding.
- Report to the U.S. Congress, via Congressional testimony or other communication formats, about the impact of The Campaign and the cost effectiveness of resources invested in The Campaign, under the authority granted by the Public Health Services Act.

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 the best available solution to CDC's evaluation objectives, within the time, cost, and feasibility constraints noted above.

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

This study will rely on Web surveys to be self-administered at a time convenient to respondents in the established GfK Knowledge Panel sample and the new ABS-sourced panel. Utilization of these sample sources and Web-based data collection provides a number of methodological advantages including increased accuracy in measurement of key variables of interest, robust sample characteristics, and reduced burden on study participants. This approach also yields significant cost efficiencies compared to other modes of data collection such as telephone surveys. These advantages include but are not limited to:

- Increased privacy. Compared to telephone interviewing, Web-based surveys reduce vulnerability to socially desirable survey responses, particularly on sensitive subjects such as tobacco use. Surveys are self-administered primarily in a private setting or in a location convenient to the respondent. Additionally, the surveys can be completed at times that are suitable for respondents, reducing disruption of their daily activities. Moreover, respondents do not speak to human interviewers as they would with telephone surveys.
- 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 any 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 accurately measure awareness of and exposure to campaign ads. By comparison, telephone surveys do not allow for direct exposure to campaign messages and stimuli, preventing more accurate measurement of individual awareness and recall of campaign ads. It has been demonstrated that the use of visual cues to prompt ad recognition (which is only possible with Web surveys) 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 CDC's National Tobacco Education 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. There are no existing data sources that contain measures on awareness of and exposure to The Tips 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.

Other in-progress data collections and existing surveillance systems such as the National Adult Tobacco Survey (OMB No. 0920-0823, exp. 7/31/2015) and the Behavioral Risk Factor Surveillance System would not be able to facilitate the precise timing of evaluation data on The Campaign and none could 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 public health impact, which is CDC's mandate.

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, specific subgroups or specific professions, 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 National Tobacco Education Campaign may impede the Federal government’s efforts to improve public health. Without the information collection requested for this evaluation study, it would be difficult to determine the value or impact of The 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 non-smokers in the U.S. 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 message testing activities fully comply 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 Federal Register Notice was published in the *Federal Register* on November 20, 2013, Volume 78, No. 224, pages 69680- 69681 (**Attachment D-1**). One public comment was received and acknowledged (**Attachment D-2**).

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 Center for Tobacco Products (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 longitudinal cohort will be offered \$20 for completion of each survey in which they participate. An additional \$30 per survey 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. Higher incentives are required 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 and for ongoing survey participation among existing KnowledgePanel participants.

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 1 to the first follow-up 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 use of modest incentives is expected to enhance survey response rates without biasing responses. A smaller incentive may not encourage sufficient survey response. Numerous empirical studies have shown that incentives can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999). We also believe that the incentives will result in higher data validity as participants will become more engaged in the survey process. This will also enhance overall response to all surveys. The use of incentives will help ensure that data collection is completed in a timely manner. 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. Because all selected individuals may not be eligible for the study, we want to ensure efficient project spending and only provide incentives to respondents after they are determined to be eligible.

A.10. Assurance of Confidentiality Provided to Respondents

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 E-1**).

Privacy Act Determination

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.

Safeguards

To ensure data security, all RTI and GfK project staff are 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 limited to project staff on a “need-to-know” basis only. GfK has developed a secure transmission and collection protocol, including the use of system passwords, and two separate sets of firewalls to prevent unauthorized access to the system. Survey responses are written in real-time directly to GfK’s server and are then stored in a local Oracle database. The database is protected primarily through firewall restrictions, password protection, and 128-bit encryption technology. Individual identifying information will be maintained separately from completed questionnaires and from computerized data files used for analysis. A detailed description of GfK privacy safeguards is provided with this submission (**Attachment F-1**). No respondent identifiers will be contained in reports to CDC and results will only present data in aggregate.

Consent

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-1**). 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.

Nature of Participation

Respondents will participate on a voluntary basis. The voluntary nature of the information collection is described in the introductory section of the screener questionnaire (**Attachment B-1**) and the initial invitation letter for ABS-sourced respondents (**Attachment G-1**) and initial contact email for KnowledgePanel respondents (**Attachment G-2**).

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, etc.), 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-1**) 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

Data collection will take place over two years in 2014 and 2015. Information will be collected through on-line surveys involving adult smokers and non-smokers in the U.S., ages 18-54. After a brief screening process to verify respondents' interest and eligibility (see **Attachment C-1**, Screening Questionnaire), a total of 5 waves of information collection are planned. Respondents who are smokers will be asked to participate in up to 5 surveys (wave 1 plus 4 follow-ups), and respondents who are non-smokers will be asked to participate in up to 4 surveys (wave 1 plus 3 follow-ups). Information collection will be initiated in early 2014, immediately upon OMB approval (see **Attachment C-2**, Smoker Wave 1 Survey, and **Attachment C-4**, Nonsmoker Wave 1 Survey). The second wave of information collection (first follow-up) is scheduled to begin approximately three months later. Thereafter, 3 subsequent follow-up surveys will be conducted quarterly with smokers, and 2 additional follow-up surveys will be conducted with non-smokers (see **Attachment C-3**, Smoker Follow-up Surveys for Waves 2-5) and **Attachment C-5**, Nonsmoker Follow-up Surveys for Waves 2-4).

CDC's data collection contractor has conducted many smoking-related surveys of similar length among smokers and non-smokers with GfK. The contractor examined diagnostic data from each of these prior surveys and estimates that the burden per response for all surveys is 30 minutes.

CDC currently plans to field identical follow-up instrument(s) in waves 2-5, however, we recognize that the relevant product market is very dynamic. It may be necessary to make adjustments to the follow-up instrument(s) in waves 2-5 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 estimated at 17,554 hours over 2 years. Because this data collection will take place in 2014 and 2015, the annualized response burden over these two years is estimated at 8,777 hours. **Exhibit 1** provides details about how response burden was estimated. The Web self-administered surveys will be designed to maximize ease of response (at home on personal computers) and thus decrease respondent burden.

Exhibit 1. 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 and Consent Process	13,074	1	5/60	1,090
Adults, ages 18-54 in the U.S.	Smoker Wave 1 Survey	4,720	1	30/60	2,360
	Smoker Follow-Up Survey (Wave 2)	1,982	1	30/60	991
	Smoker Follow-Up Survey (Wave 3)	1,982	1	30/60	991
	Smoker Follow-Up Survey (Wave 4)	1,982	1	30/60	991
	Smoker Follow-Up Survey (Wave 5)	1,982	1	30/60	991

	Nonsmoker Wave 1 Survey	1,400	1	30/60	700
	Nonsmoker Follow-Up Survey (Wave 2)	441	1	30/60	221
	Nonsmoker Follow-Up Survey (Wave 3)	442	1	30/60	221
	Nonsmoker Follow-Up Survey (Wave 4)	442	1	30/60	221
	Total				8,777

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 \$200,906. 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 Process	13,074	1,090	\$22.89	\$24,950
	Smoker Wave 1 Survey	4,720	2,360	\$22.89	\$54,020
	Smoker Follow-Up Survey (Wave 2)	1,982	991	\$22.89	\$22,684
	Smoker Follow-Up Survey (Wave 3)	1,982	991	\$22.89	\$22,684
	Smoker Follow-Up Survey (Wave 4)	1,982	991	\$22.89	\$22,684
	Smoker Follow-Up Survey (Wave 5)	1,982	991	\$22.89	\$22,684
	Nonsmoker Wave 1 Survey	1,400	700	\$22.89	\$16,023
	Nonsmoker Follow-Up Survey (Wave 2)	441	221	\$22.89	\$5,059
	Nonsmoker Follow-Up Survey (Wave 3)	442	221	\$22.89	\$5,059
	Nonsmoker Follow-Up Survey (Wave 4)	442	221	\$22.89	\$5,059
					Total

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 \$6,598,566 over 2 years or \$3,299,283 annualized. 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 2014 and 2015, thus the annual cost to the Federal government is estimated to be \$3,329,673 (\$3,299,283 RTI cost + \$30,390 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
GS-13	\$98,324	25%	\$24,581
GS-14	\$116,189	5%	\$5,809
		Subtotal, CDC Personnel	\$30,390
Contractual Costs for Data Collection and Management (RTI)		Subtotal, Contractual Costs	\$3,299,486
		Total	\$3,329,673

A.15. Explanation for Program Changes or Adjustments

In 2013, we conducted one wave of data collection for smokers and one wave of data collection for nonsmokers. All information collection occurred in a period of less than 12

months. For each survey in Phase 2, Total N = Annualized N. The total (or annualized) number of responses was 61,273 and the total (or annualized) burden hours were 8,765.

The Phase 3 evaluation (2014 – 2015) involves a smaller initial cohort of respondents and a longer follow-up period. Respondents who are smokers will participate in 5 waves of data collection, and respondents who are nonsmokers will participate in 4 waves of data collection. New ICs must be created to represent waves 2-5 of information collection.

There is a net decrease in the annualized number of responses, primarily due to a reduction in the number of respondents who will go through screening. There is a small net increase in total annualized burden hours.

Exhibit 3 summarizes changes to annualized information collection and burden.

Exhibit 3. Changes to Annualized Information Collection, 2013 to 2014-2015

Type of Respondents	Information Collection	Phase 2 Evaluation (2013)		Phase 3 Evaluation (2014-2015)		Change	
		Number of Responses	Burden Hours	Number of Responses	Burden Hours	Number of Responses	Burden Hours
General Population	Screening	43,737	1,458	13,074	1,090	(-30,663)	(-368)
Smokers	Wave 1	14,250	5,938	4,720	2,360	(-9,530)	(-3,578)
	Wave 2			1,982	991	+1,982	+991
	Wave 3			1,982	991	+1,982	+991
	Wave 4			1,982	991	+1,982	+991
	Wave 5			1,982	991	+1,982	+991
Non-smokers	Wave 1	3,286	1,369	1,400	700	(-1,886)	(-669)
	Wave 2			441	221	+441	+221
	Wave 3			442	221	+442	+221
	Wave 4			442	221	+442	+221
	Total	61,273	8,765	28,447	8,777	(-32,826)	+12

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 non-smokers in the U.S. These estimates will take the form of self-reported ad recognition and recall that assess basic exposure as well as frequency of ad exposure. These estimates will also be calculated separately for each specific Campaign advertisement. Data from this information collection will also be used to examine statistical associations between exposure to The 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 non-smokers 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.

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 1 to wave 5 as a function of increases in campaign awareness between waves 1 and 2 for the same person. This will enable stronger causal inferences of campaign 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 Power Point 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 3 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 4**.

The Campaign is scheduled to begin in February, 2014. OMB approval is requested by March 1, 2014 or as soon as possible.

Exhibit 4. Project Schedule

Project Activity	Date
Wave 1 data collection	March-June 2014
Wave 2 data collection	September-November 2014
Wave 3 data collection	January-Mar 2015
Wave 4 data collection	April-June 2015
Wave 5 data collection	July-September 2015
Preparation of analytic data file	2-4 weeks after completion of data collection
Data analysis	Ongoing beginning 2 weeks after wave 1 completion
Report writing and dissemination	Ongoing during data collection

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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