Evaluation of the National Tobacco Prevention and Control Public Education Campaign OMB No. 0920-0923 Revision

Supporting Statement Part A: Justification

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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TIME SENSITIVE

Table of Contents

Section

A. Justification

- A.1. Circumstances Making the Collection of Information Necessary
- A.2. Purposes and Use of Information Collection
- A.3. Use of Improved Information Technology and Burden Reduction
- A.4. Efforts to Identify Duplication and Use of Similar Information.
- A.5. Impact on Small Businesses or Other Small Entities
- A.6. Consequences of Collecting the Information Less Frequently
- A.7. Special Circumstances
- A.8. Comments in Response to the FR Notice and Consultation
- A.8.a. Federal Register Notice
- A.8.b Outside Consultation
- A.9. Explanation of Any Payment or Gift to Respondents
- A.10. Assurance of Confidentiality Provided to Respondents
- A.11. Justification for Sensitive Questions
- A.12. Estimates of Annualized Burden Hours and Cost
- A.13. Estimates of Annualized Respondent Capital and Maintenance Costs
- A.14. Estimates of Annualized Cost to the Federal Government
- A.15. Explanation for Program Changes or Adjustments
- A.16. Plans for Tabulation and Publication and Project Time Schedule
- A.17. Reason(s) Display of OMB Expiration Date is Inappropriate
- A.18. Exceptions to the Certification Statement

List of Exhibits

- Exhibit 1. Questionnaire Changes and Additions
- Exhibit 2. Selected OMB-Approved Studies Using the Knowledge Networks Online Panel
- Exhibit 3. Estimated One-Year Annualized Burden
- Exhibit 4. Estimated One-Year Annualized Cost to Respondents
- Exhibit 5. Project Schedule

List of Attachments

- A-1. Public Health Service Act
- A-2. Family Smoking Prevention and Tobacco Control Act
- A-3. PPHF
- B-1. Federal Register Notice
- B-2. Summary of Public Comments and CDC Response
- C-2a. Smoker Phase 2 Follow-Up Questionnaire
- C-2b. Sample Screen Shots of the Smoker Phase 2 Follow-Up Questionnaire
- D-2a. Non-Smoker Phase 2 Follow-Up Questionnaire
- D-2b. Sample Screen Shots of the Non-Smoker Phase 2 Follow-Up Questionnaire
- E-1. Screening and Consent Process (screen shots)
- E-2. Email Notifications and Reminders
- F-1. Knowledge Networks Panel Recruitment Procedures
- F-2. Knowledge Networks Privacy and Confidentiality Procedures
- G-1. RTI IRB Approval Notice
- H-1 and H-2. Reference Articles on Knowledge Networks
- I. Information Collection Instruments Used in the Phase 1 Evaluation (2012)
 - a. Attachment C-1, Smoker Baseline Questionnaire
 - b. Attachment C-2, Smoker Follow-Up Questionnaire
 - c. Attachment D-1, Non-Smoker Baseline Questionnaire
 - d. Attachment D-2, Non-Smoker Follow-Up Questionnaire

J. Primary and Secondary Outcomes, Survey Questions, and Expected Timeframe for Outcome Change

TIME SENSITIVE. OMB APPROVAL IS REQUESTED NO LATER THAN 2/28/2013. INFORMATION COLLECTION WILL BE CONDUCTED IN JUNE/JULY 2013. INFORMATION COLLECTION IS TIED TO A MEDIA CAMPAIGN SCHEDULED TO RUN IN WINTER/SPRING 2013.

Abstract

The Centers for Disease Control and Prevention's (CDC's) Office on Smoking and Health (OSH) requests a Revision of current OMB approval for the Evaluation of the National Tobacco Prevention and Control Public Education Campaign (OMB no. 0920-0923, exp. 2/28/2013). OMB approval is requested for one year. There will be a net decrease in the number of responses and the total annualized burden hours. There are no changes to the estimated burden per response.

In mid 2012, CDC conducted a web-based baseline (Wave 1) and follow-up survey (Wave 2) of smokers and non-smokers in the U.S. for purposes of evaluating the CDC's National Tobacco Prevention and Control Public Education Campaign (The Campaign) (Phase 1). CDC has used data from this information collection to examine the association between smokers' and nonsmokers' exposure to The Campaign and changes in outcome variables of interest.

Phase 2 of the Campaign is scheduled to launch in 2013. CDC will continue to use data from the 2012 baseline (Wave 1) for comparison purposes and proposes to conduct a second follow-up survey (Wave 3 of data collection) to supplement the information previously collected in 2012. The second follow-up survey to be administered in Wave 3 is a modified version of the first follow-up survey administered in 2012 with the same sample of respondents. The information to be collected in 2013 will be used to assess smokers' and nonsmokers' exposure and reactions to Phase 2 campaign messages, quit attempts made during the Phase 2 campaign, and other relevant outcomes.

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

This statement requests a Revision of OMB clearance for Evaluation of the National Tobacco Prevention and Control Public Education Campaign (OMB no. 0920-0923, exp. 2/28/2013). A baseline and a follow-up survey were conducted during the initial clearance period. OMB approval is requested for one additional year in order to field a second follow-up survey (Wave 3). The original baseline from 2012 will be retained for comparison with the second follow-up survey, with the same sample of respondents.

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 Research (CTR) in the Food and Drug Administration (FDA). 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 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. Phase 1 of this campaign, called "Tips from Former Smokers" was implemented from late March to early June 2012, and included evidence-based paid media advertising that highlights

the negative health consequences of smoking. The Campaign's primary target audience was adult smokers and it included paid advertisements that were aimed at providing support to smokers in the process of quitting, with information and other resources to increase smokers' chances of success in their attempts to quit smoking. A primary objective of The Campaign was to increase smokers' awareness of these messages as well as their knowledge about the harmful effects of smoking. A secondary audience for The Campaign was adult non-smokers. A key objective for the non-smoker audience was to encourage non-smokers to communicate with other smokers they may know (including family and friends) and encourage them to quit smoking. Additional campaign ads focused on raising awareness of the harmful effects of secondhand cigarette smoke, particularly for children. In addition to television advertisements that aired nationally from March to June 2012, The Campaign implemented complementary ads in radio, Internet, print, outdoor, and other media formats. In 2012, CDC conducted baseline (Wave 1) and follow-up (Wave 2) surveys to evaluate the reach of the Phase 1 campaign and to examine the effectiveness of these efforts in impacting specific cognitive and behavioral outcomes that were targeted by campaign ads.

Phase 2 of The Campaign will be launched in 2013 and will build on messages and ads from Phase 1. CDC proposes to conduct one additional follow-up survey in 2013 (Wave 3 of data collection) utilizing similar data collection methods and a modified version of the instrument fielded in 2012. The goal of the proposed information collection is to evaluate the reach of the Phase 2 campaign among intended audiences and to examine the effectiveness of these efforts in impacting specific cognitive and behavioral outcomes that are targeted by The Campaign. The infrastructure developed for the Phase 1 evaluation provides an efficient, low cost and low burden strategy for obtaining longitudinal and cross-sectional data to support a strong evaluation design for Phase 2 of this historic national campaign. In anticipation of future campaigns, this evaluation will enable CDC (cost-efficiently and without significant added burden) to assess attitudes and practices of smokers around the use of cigars and cigar-like products.

The proposed Wave 3 survey will facilitate repeated measures on outcomes of interest before the original Phase 1 campaign and again after the Phase 2 campaign. The evaluation

design allows CDC to estimate the reach of the Phase 2 Campaign, to gauge longer-term changes in knowledge and immediate behaviors of smokers and nonsmokers, and to generate hypotheses about the impact of the combined Phase 1 and Phase 2 Campaigns. Study design limitations similar to those described in the currently-approved OMB ICR, however, still apply and thus decrease our capacity to draw nationally representative conclusions about either smoking-related knowledge and behavior or the impact of the campaign on long-term quit rates in sub-populations. However, this design remains the best available solution to CDC's evaluation objectives.

Privacy Impact Assessment

Overview of the Information Collection

This information collection is designed to measure national awareness of and exposure to Phase 2 of the National Tobacco Prevention and Control Public Education Campaign among smokers and non-smokers in the U.S. As described in the initial OMB approval for Evaluation of the National Tobacco Prevention and Control Public Education Campaign (OMB no. 0920-0923, exp. 2/28/2013), the recent evaluation of this campaign utilized self-administered Web surveys (Waves 1 and 2) to assess Campaign awareness and relevant outcomes among smokers and nonsmokers' in the U.S. In this Revision request, the proposed additional information collection (Wave 3) will utilize the same design, relying on Web surveys to be self-administered at home on personal computers to measure smokers' and nonsmokers' exposure to the next phase of The Campaign. Respondents will be drawn from the Knowledge Networks (KN) panel, a large online panel of the U.S. population. Immediately following the conclusion of the new Phase 2 campaign, we will conduct an additional third survey wave of smokers and non-smokers from the KN panel. Because the KN panel is maintained over time, we expect a significant number of participants (approximately 70%) to be retained from the original Wave 1 baseline sample. The survey will be fielded during late June and early July immediately after the Phase 2 Campaign airs, to assess variables of interest. These include knowledge, attitudes, and beliefs related to smoking as well as intentions to quit and prior quitting behavior. The proposed data collection

timeframe is designed to ensure that awareness of the Phase 2 Campaign is measured immediately after intensive media delivery from The Campaign has taken place, minimizing the potential for decay in awareness of The Campaign. This will facilitate analysis of relationships between individuals' exposure to The Campaign and changes in outcomes of interest, including quit attempts. This design allows us to calculate changes in campaign-targeted outcomes for study participants before and after the combined Phase 1 and Phase 2 campaigns. We hypothesize that if the combined Campaign is effective, the baseline (Wave 1) to follow-up (Wave 3) changes in outcomes should be larger among individuals exposed to the combined Campaign more frequently (i.e., dose-response effects).

The KN panel will be the primary source of sample and will be used to generate a singular estimate of key outcomes across a large, geographically and socio-demographically diverse sample. The KN panel will also include additional new smokers from an expanded panel of KN smokers, sourced from an address-based sampling frame as described in the previously approved information collection request. Similar to the previous data collection, we will also include additional sample of smokers from the Survey Sampling International (SSI) online panel, which is a separate online panel of U.S. residents who participate in online surveys on an ongoing basis. SSI is one of the leading providers of online sampling in the U.S. and around the world. These data will be used to boost the overall sample sizes of smokers, enhancing statistical power to determine the effects of the combined phases of The Campaign.

Items of Information to be Collected

The survey content for Wave 3 will be very similar to the instruments fielded in the initial baseline (Wave 1) and follow-up data collection (Wave 2). This 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. The survey will also include measures of audience awareness of and exposure to The Campaign advertisements as well as measures of the aforementioned outcome variables of interest. There will be several additional items that are aimed at assessing new messages that are specific to the Phase 2 campaign. These will include items on knowledge

about other smoking-related diseases that will be featured in new Phase 2 advertisements (such as diabetes) and measures to assess smoking relapse since the original baseline survey. In addition, several items were added to assess the target audience's use and attitudes towards cigars and cigar-like products. Research indicates that, while cigarette consumption decreased 32.8% from 2000 to 2011, consumption of cigars increased 123.1% over the same period. The revised questionnaires for smokers and nonsmokers are located in **Attachment C-2a (Smoker Phase 2 Follow-Up Questionnaire) and Attachment D-2a (Non-Smoker Phase 2 Follow-Up Questionnaire).** The screening instrument used for recruiting respondents is located in **Attachment E-1**. For reference, **Attachment I** includes copies of the baseline and follow-up instruments that were fielded in Waves 1 and 2 (2012). These instruments will not be fielded in Wave 3 (2013) but are included as background for this Revision request. **Attachment J** lists outcomes of interest, expected timeframes for impact, related survey questions, and corresponding instrument item numbers.

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. None of the intervention websites have content directed to children younger than age 13. In addition, the Web-based version of the follow-up survey will only be accessible to participants of the study.

A.2. Purposes and Use of Information Collection

To date, CDC has used information collected in the initial approval period to provide the public with data on the reach of the Phase 1 campaign among adults in the U.S. as well as how adults reacted to seeing specific Phase 1 campaign ads. These data were recently presented in a public forum at the National Conference on Tobacco or Health in August, 2012 and included information on the percentage of adults who had seen specific ads, how often they were exposed to the ads, and how they responded to seeing the ads. This information has been further used to inform the development of ads for the upcoming Phase 2 campaign in early winter/spring 2013. CDC has presented these data to creative agencies that are developing Phase 2 ads now and are using this information to further refine messages strategies for the

Phase 2 campaign. The information obtained from the proposed revised data collection activities will be used in a similar way to inform CDC, policy makers, adult smokers and nonsmokers in the U.S., prevention practitioners, and researchers about the extent of adults' exposure to the Phase 2 campaign messages nationally and the extent to which exposure to these messages is associated with changes in outcomes targeted by The Campaign. Hence, the overall purposes of this third wave of information collection have not changed since the original information collection. While not exhaustive, the list below illustrates a range of purposes and uses for the proposed information collection:

- Provide critical data on the reach of The Campaign among adults in the U.S., particularly with estimates of the proportion of the population that was exposed to The Campaign.
- Understand the influence of The Campaign on attitudes, knowledge, beliefs, and behaviors around tobacco use and smoking cessation behaviors.
- Inform CDC, policy makers, and other stakeholders on the impact of The Campaign overall.
- 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.
- 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 study design and ensure that evaluation results are interpreted with appropriate care and caution. Specifically, we will include the following statement: "Study design limitations decrease our capacity to draw nationally representative conclusions about either smoking-related knowledge and behavior or the impact of the campaign on long-term quit rates in sub-populations. However the design is the best available solution to CDC's evaluation objectives, within the time, cost, and feasibility constraints."

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

This study will rely on Web surveys to be self-administered at home on personal computers. The primary Web panel we are using for this study is Knowledge Networks' KnowledgePanel[®]. Knowledge Networks utilizes address-based sampling (ABS) for its panel recruitment. When KnowledgePanel[®] began over 10 years ago, panelists were recruited via RDD telephone surveys. At the time, RDD samples allowed access to over 90% of U.S. households. This is no longer the case due to marked declines in landline households, dramatic increases in cell-only households, the use of caller ID devices and call screening, answering machines, and do-not-call lists. Hence, a change was made in 2009 to begin recruiting entirely with the U.S. Postal Service's Delivery Sequence File, which provides coverage to 97% of U.S. households. Under this recruitment procedure, randomly sampled addresses are invited to join KnowledgePanel[®] through a series of mailings and, in some cases, telephone follow-up calls to non-responders when a telephone number can be matched to the sampled address. Operationally, households invited to participate in the KnowledgePanel® have the option to join the panel one of several ways: (1) completing and returning a paper form in a postage-paid envelop; (2) calling a toll-free hotline maintained by Knowledge Networks; or (3) going to a dedicated Website and completing an online recruitment form. Once these recruitment procedures are completed, invited participants become empaneled and are available to begin participating in specific online surveys. All KN panelists complete their surveys online. See Attachment F-1 for additional details on Knowledge Networks' panel recruitment methodology.

Utilization of this online panel provides a number methodological advantages including increased accuracy in measurement of key variables of interest, attractive 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) reduces vulnerability to socially desirable survey responses, particularly on sensitive subjects such as tobacco use. Surveys are self-administered in a private setting and respondents do not speak to human interviewers as they would with telephone surveys.
- Coverage of non-Internet households Households are provided with access to the Internet and hardware if needed (free Netbook laptop and free internet service). Thus unlike Internet convenience panels, also known as "opt-in" panels, that include only individuals with Internet access who volunteer themselves for research, KnowledgePanel recruitment covers households with and without Internet access.
- ABS provides coverage to cell-phone only households.
- Flexible and timely data collection Because KN does not involve human interviewers and all ensuing requirements for interviewer training and quality control, it is easier and cheaper to launch surveys very quickly.
- Significant cost savings over traditional telephone surveys (due to lack of human interviewers and interviewer training).
- 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 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).
- KnowledgePanel[®] utilizes an unbiased general topic recruitment protocol that is free of self-selection biases related to pre-existing interests in specific research topics.

Finally, KnowledgePanel[®] has been used for a number of similar evaluation studies, including CDC media evaluation studies led by RTI. *Exhibit 2* lists selected OMB-approved studies that have utilized Knowledge Networks' KnowledgePanel[®].

Sponsoring Agency	OMB Approval Number	Approval Date	Study Name	Data Collection Contractor	Contact Person
HHS-OPA	0990- 0345	9/9/2009	Evaluation of the Parents Speak Up National Campaign: National Media Tracking Surveys	RTI International	Kevin C. Davis
HHS-OPA	0990- 0325	8/15/2008	Evaluation of the Parents Speak Up National Campaign: Children's Study	RTI International	Kevin C. Davis
HHS-CDC	0920- 0752	8/24/2007	Examining the Efficacy of the HIV Testing Social Marketing Campaign for African American Women	RTI International	Kevin C. Davis
HHS-OPA	0990- 0311	6/7/2007	Evaluation of the National Abstinence Media Campaign	RTI International	Kevin C. Davis
HHS-CDC	0920- 0565	8/19/2002	Reactions to Canadian Style Cigarette Warning Labels	RTI International	Carol Prindle and Paul Mowery
Environmenta l Protection Agency	2090- 0024	1/22/2004	Estimating the Value of Improvements to Coastal Waters— A Pilot Study of a Coastal Valuation Survey	RTI International	George L. Van Houtven
Environmenta	2060-	2/19/2003	Eliciting Risk	RTI	George L.

Exhibit 2. Selected OMB-Approved Studies Using the Knowledge Networks Online Panel

l Protection Agency	0502		Tradeoffs for Valuing Fatal Cancer Risks	International	Van Houtven
Environmenta l Protection Agency	2010- 0031	10/2002	Water Quality in America Pretest Round 1	Harvard University, Law School	Kip Viscusi
Environmenta l Protection Agency	2010- 0031	2/2003	Water Quality in America Pretest Round 2	Harvard University, Law School	Kip Viscusi
Environmenta l Protection Agency	2010- 0031	4/2003	Water Quality in America Pretest Round 3	Harvard University, Law School	Kip Viscusi
Environmenta I Protection Agency	2010- 0031	4/2004	Water Quality in America Main Interview	Harvard University, Law School	Kip Viscusi
United States Department of Agriculture	0536- 0062	12/16/2003	Estimating Consumer Benefits of Improving Food Safety	Harvard University, Center for Risk Analysis, Department of Health Policy and Management	James K. Hammitt
United States Department of Agriculture	0536- 0062	3/11/2005	Estimating Consumer Benefits of Improving Food Safety	University of Wyoming, Department of Economics and Finance	Jason F. Shogren
National Oceanic and Atmospheric Agency	0648- 0531	11/16/2005	Coral Reef Economic Valuation Pretest	Stratus Consulting	David Chapman

A.4. Efforts to Identify Duplication and Use of Similar Information

Phase 2 of CDC's National Tobacco Prevention and Control Public Education Campaign will be implemented in early winter/spring 2013. There are no existing surveillance sources that contain measures on awareness of and exposure to The Campaign that would measure realworld exposure to The Campaign in early 2013. This proposed information collection therefore does not duplicate previous efforts. Rather, this effort builds on the existing Wave 1 baseline data that has been collected under the currently-approved information collection to yield additional follow-up data that allows pre-post analysis of the cumulative Phase 1 and Phase 2 campaigns. In designing the proposed data collection activities, we have taken several steps to ensure that this effort does not duplicate ongoing efforts and that no existing data sets would address the proposed study questions. We have carefully reviewed existing data sets to determine whether any of them are sufficiently similar or could be modified to address CDC's need for information on the effectiveness of The Campaign with respect to promoting attempts to quit smoking among smokers. We investigated the possibility of using existing data to examine our research questions, such as data collected as part of ongoing national surveillance systems; evaluations of current or past state-level campaigns describing the harms of tobacco; the National Adult Tobacco Survey; and the Behavioral Risk Factor Surveillance System. Due to the early 2013 timing of The Campaign, none of these existing data sources will be able to facilitate pre- and post-test data on The Campaign, none will include the necessary in-depth survey questions on awareness of individual ads and other campaign materials, and none contain all of the necessary outcome variables specific to The Campaign's messages. It should also be noted that while the FDA conducts health communications work, this information collection is not duplicative since the CDC is the specific Operating Division that has been tasked with implementing and evaluating the aforementioned campaign.

A.5. Impact on Small Businesses or Other Small Entities

Respondents in this study will be members of the general public, specific subpopulations or specific professions, not business entities. No impact on small businesses or other small entities is anticipated.

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." Lack of information needed to evaluate the National Tobacco Prevention and Control Public Education Campaign may impede the Federal government's efforts to improve public health. Without the information collection requested for this evaluation study, it would be difficult to determine the value or impact of The 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 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 and data collection should coincide with each successive implementation of additional Campaign phases. We believe that the proposed additional survey will provide sufficient data to effectively evaluate the next phase of The Campaign at a much lower cost to the government than the costs of initiating a separate new evaluation.

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 CRF 1320.5 (d)(2). There are no special circumstances. 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 October 15, 2012, Volume 77, No. 199, pages 62516-62517 (**Attachment B-1**). One Public Comment was received stating that the National Tobacco Education Campaign is obsolete and the funds would be better spent on other health problems like autism. CDC provided a courtesy reply to this

comment (Attachment B-2).

A.8.b. Consultation

The following individuals inside the agency have been consulted on the design of The Campaign evaluation plan, audience questionnaire development, or intra-agency coordination of information collection efforts:

Tim McAfee, MD, MPH Office on Smoking and Health Centers for Disease Control and Prevention 4770 Buford Highway NE, Mailstop K50 Atlanta, GA 30341 Phone: (770) 488-5709 Email: <u>mtt4@cdc.gov</u>

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Jeffrey McKenna, MS National Center for Chronic Disease Prevention and Health Promotion Centers for Disease Control and Prevention 4770 Buford Highway NE, Mailstop K40 Atlanta, GA 30341 Phone: (770) 488-5131 Email: Jwm0@cdc.gov

The following individuals outside of the agency have been consulted on the audience questionnaire development. CDC OSH holds regular by-weekly meetings with FDA CTR where updates on The Campaign are included as a standing agenda item. Additionally input has been solicited and received from FDA on the design of this study including participation by FDA on a call with OMB on November 17, 2011 (Message Testing for Tobacco Communication Activities (MTTCA) *Previous Title: "Testing and Evaluation of Tobacco Communication Activities"*).

Kevin C. Davis, MA

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Donna Vallone, PhD Legacy Foundation 1724 Massachusetts Avenue, NW Washington, DC 20036 Phone: (202) 454-5783 Email: <u>dvallone@legacyforhealth.org</u>

April Brubach FDA, Center for Tobacco Products 9200 Corporate Boulevard Rockville, MD 20850 Phone: (301) 796-9214 Email: april.brubach@fda.hhs.gov

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

Payments for participation in the proposed Wave 3 follow-up study will adhere to the same incentive amounts used in the previous Wave 1 information collection. Participants from the KN panel will be offered 15,000 bonus points (equivalent to \$15 cash) for completion of the proposed follow-up survey. Participants from the SSI supplemental sample will be offered \$3 for completion of the proposed follow-up survey. These incentive structures are customary for each panel and are known by participants ahead of time. KN panel incentives are generally higher because KN maintains a longer-term panel with fewer participants. Therefore, they offer higher incentives for fewer surveys in order to maintain consistent participation among their panelists over time and to minimize panel attrition. The lower SSI panel incentive reflects the

"opt-in" nature of this panel, as opt-in panels are comprised of volunteer participants and generally involve shorter-term participation but more frequent surveys. Alterations to each respective incentive structure would not be advised as this would de-stabilize each sample vendor's ability to estimate sample response and project the yield of completed interviews.

The incentives are intended to recognize the time burden placed on participants, encourage their cooperation, and to convey appreciation for contributing to this important study and are similar to incentives that are offered for most surveys among participants in each respective panel. 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 based on the need to ensure high retention from baseline to follow-up in order to retain the necessary analytic power of the longitudinal sample. The higher incentive (\$15 for KN panel, \$3 for SSI) for the follow-up survey is implemented particularly to ensure sufficient participation and retention among individuals who completed the original baseline survey, prior to the launch of the Phase 1 Campaign.

The use of modest incentives is expected to enhance survey response rates without biasing responses. A smaller incentive would not appear sufficiently attractive to participants. We also believe that the incentives will result in higher data validity as participants will become more engaged in the survey process. This will also enhance overall response to the survey. It is crucial that the Wave 3 survey be completed very soon after the end of the Phase 2 Campaign as this is central to our planned data analyses. 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 Knowledge Networks, which found that use of similar incentives increased response rates among adults, particularly for retention in longitudinal studies. All respondents in the KN panel are given free hardware (if needed), free Web access (if needed), free e-mail accounts (if needed), and ongoing technical support as pre-incentives by Knowledge Networks. Because all selected individuals may not be eligible for the study, we want to ensure sufficient project spending and only provide bonus point 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 proposed changes to the instruments and follow-up data collection plans (see RTI IRB amendment approval notice in **Attachment G**).

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 Knowledge Networks. The response data transmitted from Knowledge Networks to RTI International, the data analysis contractor, will be de-identified prior to transmission and analysis.

<u>Safeguards</u>

To ensure data security, all RTI and Knowledge Networks 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. Knowledge Networks 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. Neither questionnaires nor survey responses are stored onto the Knowledge Networksprovided laptops; questionnaires are administered dynamically over the Internet. Survey responses are written in real-time directly to Knowledge Networks' 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 Knowledge Networks privacy safeguards is provided with this submission (**Attachment F-2**). No respondent identifiers will be contained in reports to CDC and results will only present data in aggregate.

<u>Consent</u>

All respondents will be assured that the information they provide will be maintained in a secure manner and will be used only for the purpose of this research. Please refer to the assurances and study descriptions that are included in the Screener and Consent Process (**Attachment E-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 and Consent Process (**Attachment E-1**) and the initial contact email (**Attachment E-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

protocol (**Attachment E-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.

A.12. Estimated Annualized Burden Hours and Cost

A.12.a. Estimated Annualized Burden to Respondents

In this Revision ICR, response burden is only estimated for the Phase 2 follow-up questionnaires that will be administered in 2013. The baseline surveys administered in 2012 will be discontinued in 2013.

Information will be collected through on-line interviews involving adult smokers and non-smokers in the U.S., ages 18-54. Information will be collected shortly after the end of the Phase 2 Campaign in early 2013. The target number of complete post-campaign interviews for smokers is 14,250 (see **Attachment C-2a**, Smoker Phase 2 Follow-Up Questionnaire). The target number of complete interviews for non-smokers is 3,286 (see **Attachment D-2a**, Non-Smoker Phase 2 Follow-Up Questionnaire). Sample screen shots of each questionnaire are provided in **Attachment C-2b** and **Attachment D-2b**. For both respondent groups, the estimated burden per response is 25 minutes.

To recruit the target number of complete interviews, we estimate that a total of 43,737 respondents must be contacted through the initial screening and consent process (**Attachment E-1**). The estimated burden per response for screening and consent is two minutes.

All respondents who are non-smokers will be drawn from the Knowledge Networks panel. Respondents who are smokers will be drawn from both the Knowledge Networks panel and the SSI panel. The same data collection instrument will be used for all respondents who are smokers. Additional information about the KN panel, SSI panel, and estimated response rates is provided in Section B.1.

This newly-proposed Wave 3 data collection will take place in 2013 only. The additional response burden for the newly-proposed Phase 2 survey is estimated at 8,765 hours. *Exhibit 3* provides details about how this estimate was calculated. The Web self-administered surveys will be designed to maximize ease of response (at home on personal computers) and thus decrease respondent burden.

Type of	E N	Number of	Number of Responses per	Average Burden per Response (in	Total Burden (in
Respondent	Form Name	Respondents	Respondent	Hours)	Hours)
General Population	Screening and Consent Process (Phase 2 Survey)	43,737	1	2/60	1,458
Adults, ages 18-54 in the U.S.	Smoker Phase 2 Follow-Up Questionnaire	14,250	1	25/60	5,938
	Non-Smoker Phase 2 Follow- Up Questionnaire	3,286	1	25/60	1,369
				Total	8,765

Exhibit 3. Estimated Annualized Burden Hours

A.12.b. Estimated Annualized Burden Costs

Respondents participate on a purely voluntary basis and, therefore, are subject to no direct costs other than time to participate. There are also no start-up or maintenance costs. RTI has conducted many smoking-related surveys of similar length among smokers and nonsmokers with Knowledge Networks. We have examined diagnostic data from each of these prior surveys and estimate that data collection for this study will take approximately 25 minutes per respondent. According to the U.S. Department of Labor (DOL) Bureau of Labor Statistics as of March 2011 the national average hourly wage is \$22.89. Thus assuming an average hourly wage of \$22.89, the estimated one-year annualized cost to participants will be \$200,631. The estimated value of respondents' time for participating in the information collection is summarized in **Exhibit 4**.

Type of		Number of	Total Burden	Hourly Wage	
Respondent	Form Name	Respondents	Hours	Rate	Total Cost
General Population	Screening and Consent Process (Phase 2 Survey)	43,737	1,458	\$22.89	\$33,374
Adults, Ages	Smoker Phase 2 Follow-Up Questionnaire	14,250	5,938	\$22.89	\$135,921
18-54 in the U.S.	Non-smoker Phase 2 Follow-Up Questionnaire	3,286	1,369	\$22.89	\$31,336
			•	Total	\$200,631

Exhibit 4. Estimated One-Year Annualized Cost

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 additional data collection are \$2,053,330. 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 additional information collection will occur in 2013, thus the annual cost to the Federal government is estimated to be \$2,096,533 (\$2,053,330 + \$43,203 CDC cost). Three CDC health communications specialists are responsible for overseeing the content of this information collection, overall project management, and coordination with other CDC activities.

ľ	temized Cost to the	e Federal Governmen	t
CDC Staff Member	Annual Salary	% Allocation (Annualized	Cost
GS-12	\$86,280	25%	\$21,570
GS-13	\$108,299	15%	\$16,245
GS-14	\$107,770	5%	\$5,389
		Subtotal, CDC Personnel	\$43,203
Contractual Costs for Data Collection and Management (RTI)		Subtotal, Contractual Costs	\$2,053,330
		Total	\$2,096,533

A.15. Explanation for Program Changes or Adjustments

There will be an increase in the number of respondents (from 34,660 to 43,737) for the Phase 2 Screening and Consent Process (**Attachment E-1**); an increase in the number of respondents (from 5,000 to 14,250) for the Smoker Phase 2 Follow-Up Questionnaire (**Attachment C-2a**); and an increase in the number of respondents (from 2,000 to 3,286) for the Non-Smoker Phase 2 Follow-Up Questionnaire (**Attachment D-2a**). However, because we will discontinue use of the Smoker Baseline Questionnaire and the Non-Smoker Baseline Questionnaire (which were fielded during the initial Phase 1 clearance period), there will be a net reduction of 1,250 burden hours for the Phase 2 Revision request.

	Phase	1	Phase	2	
Type of Data	No.	Burden	No. of	Burden	Net Change in
Collection	Respondents	Hours	Respondents	Hours	Burden Hours
Screening and	34,660	1,155	43,737	1,458	+303
Consent Process					

Smoker Baseline	11,600	4,833	N/A	N/A	-4,833
Questionnaire					
Non-Smoker Baseline	2,666	1,111	N/A	N/A	-1,111
Questionnaire					
Smoker Follow-Up	5,000	2,083	14,250	5,938	+3,855
Questionnaire					
Non-Smoker Follow-	2,000	833	3,286	1,369	+736
up Questionnaire					
Total		10,015		8,765	-1,250

A.16. Plans for Tabulation and Publication and Project Time Schedule

Data from this third wave of information collection will be used to estimate awareness of and exposure to the Phase 2 Campaign among a geographically and demographically varied population of smokers and non-smokers in the U.S. These estimates will take the form of selfreported 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. The KN panel will be the primary source of sample for describing campaign awareness for a large, varied national sample. As described previously, the KN panel alone may not be sufficient to assess awareness at more granular levels that may receive higher overall doses of the media campaign. In order to describe campaign awareness among smokers in smaller areas with relatively larger campaign doses, we will add sample. The added sample will be obtained from a separate internet panel (SSI) as well as additional ABS-sourced smokers within the KnowledgePanel^{*}. Specifically, we will collect an additional 14,250 interviews of smokers from the KN and SSI panels to participate as well as an additional 3,286 interviews of nonsmokers solely from the KN panel.

Data from this information collection will also be used to examine statistical associations between cumulative (Phase 1 + Phase 2) exposure to The Campaign and Wave 1 to Wave 3 changes in specific outcomes of interest. There are three domains of primary outcomes for this evaluation – (1) campaign awareness and receptivity, (2) awareness of cessation services, and (3) cessation-related behaviors. Based on previous empirical research, these outcomes are expected to change over longer periods of of time (within approximately 12 months),

commensurate with the longer duration of the combined Phase 1 and Phase 2 Campaigns. There are also three domains of secondary outcomes. These include (1) cessation-related communication with smokers, (2) smoking and cessation-related knowledge, attitudes, and policies, and (3) cessation-related intentions. As discussed elsewhere in this information collection request, national estimates of these outcomes will generally be derived from the KN sample alone whereas separate estimates for smaller geographic regions (such as groups of markets that receive specific dose levels of the Campaign) may be derived from the combined KN and SSI samples.

Analysis of the relationship between exposure to cumulative Phase 1 and Phase 2 Campaign and changes in these outcomes will be accomplished with the use of multivariate models that estimate Wave 3 follow-up measures of each relevant outcome as a function of prior self-reported exposure to The Campaign, controlling for baseline Wave 1 measures of each outcome as well as baseline individual characteristics that may confound the relationship between Campaign exposure 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 The Campaign, knowledge, attitudes and beliefs related to smoking, intentions to smoke, and making an attempt to quit smoking. The primary outcomes of interest among non-smokers will include awareness of The Campaign and encouragement of family or friends who smoke to quit smoking, as well as knowledge, attitudes, and beliefs related to smoking and secondhand smoke. We hypothesize that there should be larger changes in outcomes among individuals who are exposed to The Campaign more frequently (i.e., dose-response effects) .

We will also utilize measures of market-level campaign intensity, which will be constructed with available data on campaign gross ratings points (GRPs) for each market covered by this survey. GRPs are the advertising industry's standard for quantifying reach and frequency of exposure to an advertising campaign in a given media market. GRPs are based on broadcast ratings in the markets where the commercials air and provide an estimate of the percentage of the target audience that is exposed to the ads and the frequency with which they

are exposed. For example, if 80% of the target audience in a media market saw a commercial four times in a given time period, this would translate into 320 GRPs (i.e., 80 × 4) for that period. GRPs are calculated for each of the 210 designated market areas (DMAs) in the U.S. DMAs are a standard geographic unit comprised of U.S. counties that are grouped together within television market viewing areas. U.S. counties are assigned to only one DMA. Because these data represent averages within each media market, GRPs represent an individual's potential exposure to The Campaign. An individual's actual exposure may be more or less than the average represented by the GRP based on TV viewing habits.

GRP data serves two purposes. First, it allows us to examine in more detail the reach of The Campaign across media markets in the U.S. Second, it provides an alternative measure of exposure to The Campaign that is exogenous to the individual. This helps address the potential limitations of selective attention bias that may be present with self-reported awareness whereby smokers that already are already in the process of quitting may also be more attentive to campaign ads and thus more likely to indicate ad recognition. Thus we are able to use this data to check the robustness of campaign effects across different measures of exposure and to examine the validity of individual self-reported measures of exposure. That is, market-level campaign intensity should be correlated with individual-level self-reported exposure.

The GRP data will be merged to the survey data based on DMA geographic identifiers which are known for each survey participant via pre-existing panel profile information for both KN and SSI. That is, each individual in the survey will be assigned a value of campaign GRPs equal to the total GRP that was delivered over the course of The Campaign in the media market where they reside. In this way, the GRPs serve as an exogenous and naturally-varying measure of campaign "dose" among our survey participants. This will allow us to analyze the relationship between the market-level delivery of The Campaign and actual levels of awareness in each sample that is collected. This will also facilitate further analyses of the relationship between exogenous market-level measures of campaign dose and changes in the aforementioned outcome variables of interest.

It should be noted that while the KN panel's recruitment procedures are designed to approximate a nationally representative sample, the limitations associated with the panel

decrease our capacity to draw nationally representative conclusions about either smokingrelated knowledge and behavior or the impact of the campaign on long-term quit rates in subpopulations. Although KN panelists must be invited to participate and cannot volunteer on their own, there may be systematic differences between individuals who choose to join an ongoing internet panel and the type of individuals who do not wish to participate in either an internet panel and/or over an ongoing committee. In addition, while Knowledge Networks goes to great lengths to ensure that persons who are not web-users are included in the sample, the web medium may introduce some bias towards panelists more comfortable with web-based communication. Furthermore, our estimates for smaller geographic areas are even more limited with respect to representativeness because we will only be adding smokers who agreed to be in a separate ongoing panel, and we anticipate the response rate will be about 1/3 lower than that of the KN panel. 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. In recognizing the aforementioned data limitations, all communications about the evaluation results via these publication formats will carefully enumerate and describe those data limitations and ensure that evaluation results are interpreted with appropriate care and caution. The key events and reports to be prepared are listed in Exhibit *5*.

The Campaign is scheduled to begin in early winter/spring, 2013. Wave 3 information collection must begin soon after the conclusion of the Phase 2 Campaign to ensure accurate measurement of recent exposure and receptivity to The Campaign. OMB approval for this revised information collection is requested by February 28, 2013.

Exhibit 5. Project Schedule

Project Activity	Date
Phase 2 data collection	June/July 2013
Preparation of analytic data file	2-4 weeks after completion of data collection (Apx. July 2013)
Data analysis	Apx. July-September, 2013
Report writing and dissemination	Apx. October-January, 2014

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.

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