Information Collection Request

Revision of a Currently Approved Collection

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

OMB Control No. 0920-1083

Supporting Statement: Part A

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Supporting Statement: Summary

- Goal of the Study: This information collection request will enable Centers for Disease
 Control and Prevention (CDC) to continue to measure exposure and awareness of the *Tips*From Former Smokers® campaign (*Tips*) and to evaluate its impact on campaign-targeted
 outcomes among smokers and nonsmokers in the United States. This information collection
 request is a revision of a currently approved collection of a longitudinal web-based survey.
- **Intended use of the resulting data:** The information collected will be used to evaluate the effectiveness of *Tips* and to help inform the development of *Tips* in future years. Endpoints will include the reach of *Tips* among target audiences and the impact of *Tips* on quit attempts among smokers and other key outcomes.
- **Methods to be used to collect:** Data will be collected via an ongoing longitudinal webbased survey of adult smokers and nonsmokers, recruited from a probability sample of U.S. households. All surveys will be self-administered online. Data will be collected in 3 survey waves per year. Respondents may complete more than one survey wave but will only provide one response per wave (up to 3 responses per year).
- **The subpopulation to be studied:** Smokers and nonsmokers in the United States ages 18 years or older.
- **How data will be analyzed:** Descriptive and bivariate analysis will be used to summarize campaign awareness and other key variables collected. Multivariate logistic regressions will be used to estimate outcome variables of interest controlling for other confounding variables measured in the survey.

A. JUSTIFICATION

1. <u>Circumstances Making the Collection of Information Necessary</u>

The Centers for Disease Control and Prevention (CDC) requests OMB approval for a Revision of a currently approved information collection request (ICR) entitled "Extended Evaluation of the National Tobacco Prevention and Control Public Education Campaign." This work is authorized under the Public Health Service Act (41USC 241) Section 301 (**Attachment A-1**) and the Patient Protection and Affordable Care Act (**Attachment A-3**). Approval is requested for 3 years in order to assess anticipated future implementations of *Tips From Former Smokers*® (*Tips*®).

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

In 2012, the Department of Health and Human Services (HHS)/CDC launched the National Tobacco Prevention and Control Public Education Campaign (*Tips*). The primary objectives of *Tips* are to encourage smokers to quit smoking and to encourage nonsmokers to communicate with smokers about the dangers of smoking. *Tips* airs annually in all U.S. media markets on broadcast and national cable TV as well as other media channels including digital video, online display and banners, radio, billboards, and other formats. *Tips* ads rely on evidence-based paid media advertising that highlights the negative health consequences of smoking. *Tips*' primary target audience is adult smokers; adult nonsmokers constitute the secondary audience. *Tips* paid advertisements are aimed at providing motivation and support to smokers to quit, with information and other resources to increase smokers' chances of success in their attempts to quit smoking. A key objective for the nonsmoker audience is to encourage nonsmokers to communicate with smokers they may know (including family and friends) about the dangers of smoking and to encourage them to quit. *Tips* ads also focus on increasing audience's knowledge of smoking-related diseases, intentions to quit, and other related outcomes.

The goal of the proposed information collection is to evaluate the reach of *Tips* among intended audiences and to examine the effectiveness of these efforts in impacting specific outcomes that are targeted by *Tips*, including quit attempts and intentions to quit among smokers, nonsmokers' communications about the dangers of smoking, and knowledge of smoking-related diseases among both audiences. This will require customized surveys that will capture all unique messages and components of *Tips*. Information will be collected through Web surveys to be self-administered by adults 18 and over on computers in the respondent's home or in another convenient location. Evaluating *Tips*' impact on behavioral outcomes is necessary to determine campaign cost effectiveness and to allow program planning for the most effective campaign outcomes. Because *Tips* content changes, it is necessary to evaluate each yearly implementation of *Tips*.

2. Purpose and Use of Information Collection

CDC uses an iterative process of developing new concepts for ads, disseminating them through *Tips*, and then evaluating their impact to document their effectiveness, as well as to inform future implementations of *Tips*. *Tips* is evaluated with an ongoing annual longitudinal survey of smokers and nonsmokers in the United States, conducted approximately 3 times per year. As a historical perspective, to evaluate *Tips*, CDC obtained OMB approval for information collections beginning in 2012 and continuing through 2015. More recent campaign implementations from 2016 to 2019 are being evaluated with additional waves of survey data under the currently approved information collection (OMB No. 0920-1083, exp. 2/29/2020). Although analyses of these most recent data from 2018 are ongoing, preliminary results have shown that approximately 80% of the smoker population in the United States was aware of *Tips* and there were larger increases in cigarette cessation among those who were exposed to *Tips* more frequently.

Additional survey data collection is needed to continue CDC's evaluation of the *Tips* campaign in 2020 and beyond. The additional survey data will be needed to measure exposure to and awareness of each campaign among smokers and nonsmokers as well as key campaign-targeted outcomes including quit attempts among smokers, nonsmokers' communications about the dangers of smoking, and knowledge of smoking-related diseases, among others. Data on these measures will be used to analyze the relationship between exposure to *Tips* and changes in these key outcomes. These analyses will be conducted with a range of statistical methods including multivariate regressions that will estimate changes in campaign-targeted outcomes as a function of campaign exposure.

We are seeking approval to continue the mandated evaluation of the ongoing annual *Tips* campaign for an additional 3 years. The proposed information collection will include 3 survey collections per year (9 surveys in total) generally conducted before, during, and after *Tips* in each year. Using the same methods outlined in the currently-approved information collection, participants will be recruited from two sources: (1) an online longitudinal cohort of adult smokers and nonsmokers, sampled randomly from postal mailing addresses in the United States (address-based sample, or ABS); and (2) the existing GfK/Ipsos (formerly GfK) KnowledgePanel, an established long-term online panel of U.S. adults. The ABS sample will be recruited by GfK/Ipsos, utilizing nearly identical recruitment methods that are used in the recruitment of KnowledgePanel (see **Attachment F**). ABS-sourced participants will make up approximately 65% of the total sample between smokers and nonsmokers (35% will originate from KnowledgePanel). The GfK/Ipsos KnowledgePanel will be used in combination with the ABS-sourced cohort to support larger sample sizes that will allow for more in-depth subgroup analysis, such as racial/ethnic minorities, which is a key objective for CDC. All online surveys, regardless of sample source, will be conducted via the GfK/Ipsos KnowledgePanel Web portal for self-administered surveys.

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

The screening instrument used for recruiting respondents is located in **Attachments C-1** and C-2, which contains mock screenshots of the English and Spanish screening instruments, respectively. The screening tool is only administered for recruiting participants. The Waves A-I English and Spanish questionnaires for smokers are in **Attachments D-1 and D-2**, respectively, which provide mock screenshots of the smoker surveys in each language. We have also provided in **Attachment D-3** an outline of changes that have been made to the currently approved instrument. This attachment includes details on currently-approved wording, revised item wording, and justification for each specific change. These changes have also been transferred to the final Spanish version of the instrument. The nonsmoker English and Spanish questionnaires are in **Attachments E-1** and **E-2**, respectively. We have also summarized changes that have been made to the currently approved nonsmoker instrument in Attachment E-3. Final screenshots of the instruments will be shared with OMB as soon as the survey is programmed and tested by the data collection staff. Only new ABS participants recruited to replenish the sample are asked the full set of demographics and profile information. Previous participants are not queried on demographics except for things that can potentially change (e.g., education, income, and marital status). Questions to assess demographic characteristics are aligned to mirror the existing GfK/Ipsos KnowledgePanel profile questions so as not to burden participants of this panel with additional questions (e.g., assessment of sexual orientation).

3. Use of Improved Information Technology and Burden Reduction

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

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

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

4. Efforts to Identify Duplication and Use of Similar Information

Tips 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 *Tips* messages. Knowledge and attitudinal constructs specific to each campaign are assessed. There are no existing data sources that will contain measures on awareness of and exposure to annual airings of *Tips* in 2020 and beyond. Hence, the proposed information collection does not duplicate previous efforts.

In designing the proposed data collection activities, we have taken several steps to ensure that this effort does not duplicate ongoing efforts and that no existing data sets would address the proposed evaluation questions. Notably, we have coordinated closely with the Food and Drug Administration's (FDA) Center for Tobacco Products (CTP), which is responsible for carrying out the Family Smoking Prevention and Tobacco Control Act of 2009 (see **Attachment A-2**). Under this Act, FDA has broad authority to regulate the manufacturing, distribution, and

marketing of tobacco products. We have carefully reviewed a similar data collection activity by FDA (see OMB No. 0910-0753, Evaluation of the FDA's General Market Youth Tobacco Prevention Campaign, exp. 9/30/2019). This current information collection request is intended for evaluation of CDC's campaign which is targeted for adults aged 18 – 54 years, whereas FDA's campaign is targeted to youth ages 11 – 16 years at baseline (ages 13 - 18 by the end of the evaluation data collection). Distinct ad campaigns have been developed for the adult and youth audiences. As a result of the specific characteristics of the respondent population for each campaign and each evaluation activity, there is no duplication of effort for the CDC and FDA information collections. However, CDC shared a draft of this information collection plan with the FDA to ensure alignment of question wording on the instruments where topics of mutual interest are included. CDC plans to share its evaluation findings with FDA.

The in-progress Population Assessment of Tobacco and Health (PATH) study (OMB No. 0925-0664, exp 08/31/2018) is a large, national, representative longitudinal cohort study of tobacco use and health in the United States sponsored by the FDA which measures tobacco use behaviors and related health effects. This data collection cannot be modified to be fielded during on and off periods of *Tips*, in addition it is not designed to measure awareness and exposure to *Tips*.

We have also reviewed other existing data collection plans by CDC. Other in-progress CDC data collections and existing surveillance systems such as the Behavioral Risk Factor Surveillance System (OMB No. 0920-1061, exp. 3/31/21) would not be able to facilitate the precise timing of evaluation data on *Tips*; are not longitudinal studies; and could not be adequately modified to include the necessary breadth of survey questions on awareness of individual ads and on the outcomes that are important for assessment of *Tips*.

It is anticipated that implementations of *Tips* in 2020 and beyond will implement new ads that have not aired previously. Given the government's potential investments in the *Tips* campaign, it is necessary to document its effectiveness in each year of implementation. Therefore, the ongoing evaluation of *Tips* will not represent a duplication of previous efforts.

5. Impact on Small Business or Other Small Entities

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

6. <u>Consequences of Collecting the Information Less Frequently</u>

Without the information collection requested for this evaluation study, it would be difficult to determine the value or impact of *Tips* on the lives of the people it is intended to serve. Failure to collect these data could reduce effective use of CDC's program resources to benefit the health of smokers and nonsmokers in the United States.

Careful consideration has been given to how frequently *Tips*' intended audience should be surveyed for evaluation purposes. Because the proposed information collection consists of a longitudinal cohort, participants will respond up to 9 times with one response per data collection.

Responses will occur approximately 3 times per year during the approved information collection period. This schedule of information collection is designed to accommodate a 3-wave survey design in each campaign year to facilitate pre-, during-, and post-campaign measurement of key outcomes. This design maximizes the CDC's ability to measure campaign-related changes in outcomes and to fully execute analytic plans for the evaluation each year. We believe that the proposed information collection will provide sufficient data to effectively evaluate *Tips* without creating undue burden on respondents.

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

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

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

8.a Federal Register Notice

A 60-day Federal Register Notice was published in the Federal Register on April 23, 2019, vol. 84, No. 78, pp. 16863-16865 (see Attachment B). No public comments were received.

8.b Consultations

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

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

9. Explanation of Any Payments or Gift to Respondents

Participants recruited to the ABS-sourced sample and who already have internet access in their home will receive \$20 for completion of each survey. ABS-sourced respondents who do not have Internet access, and must seek out public computers or other types of internet access to complete the online surveys, will receive \$40. The level of incentive for non-Internet households is meant to encourage their participation and appropriately acknowledge their travel and effort in seeking a computer with Internet access. Participants recruited from the existing KnowledgePanel will be offered 15,000 KP bonus points (equivalent to \$15 cash), which are credited to the KnowledgePanel participant's account and redeemable for merchandise or cash in increments of \$5 or more. This is utilized to maintain consistency of survey response within KnowledgePanel.

The incentives are intended to convey appreciation for contributing to this important evaluation. Numerous empirical studies have shown that incentives can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999). The decision to use incentives for this study is further justified by the need to ensure high retention of unique respondents from survey to survey in order to retain the necessary analytic power of the longitudinal study. The higher incentive for respondents in the ABS-sourced longitudinal cohort is needed to encourage participation among individuals who do not have previous long-term experience with online surveys or panels and who may have barriers to participation, such as lack of convenient in-home access to the Internet. The proposed incentive plan represents a continuation of the incentives previously approved for this information collection (OMB No. 0920-1083, exp. 2/29/2020).

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

System of Records Under Privacy Act

Personally identifiable information (PII) including email addresses and home addresses will be collected for purposes of facilitating follow-up contact and invitations for future surveys and for distributing survey incentives via mail to the survey respondents. This information is independently collected and managed by GfK/Ipsos for the KnowledgePanel portion of the sample. PII will also be collected for the ABS portion of the sample, to be used for the same

purposes of incentive distributions and follow-up contact. 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/Ipsos, and is not collected as part of this ICR. The response data transmitted from GfK/Ipsos to RTI International, the data analysis contractor, will be de-identified prior to transmission and analysis. These data will also remain de-identified when transmitted from RTI International to the CDC. All information provided by respondents will be kept private and secure to the extent permitted by law.

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

The mechanism that will be used for notice or consent is called The Screening & Consent Questionnaire (see English and Spanish versions in **Attachments C-1 and C-2**, respectively), and will apprise respondents that participation is voluntary and that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer. Participants may opt out of the survey at any time. The voluntary nature of the information collection is described in the introductory section of the screener questionnaire (**Attachments C-1** and **C-2**) and the initial invitation letter for ABS-sourced respondents (**Attachment I-1**) and initial contact email for KnowledgePanel respondents (**Attachment I-2**).

All respondents will be assured that the information they provide will be maintained in a secure manner and will be used only for the purpose of this evaluation. Please refer to the assurances and study descriptions that are included in the English and Spanish language screening instruments (**Attachments C-1** and **C-2**, respectively). Respondents will be assured that their answers will not be shared with family members and that their names will not be reported with responses provided. Respondents will be told that the information obtained from all of the surveys will be combined into a summary report so that details of individual questionnaires cannot be linked to a specific participant.

To ensure data security, all RTI and GfK/Ipsos project staff will be required to adhere to strict standards and to sign a non-disclosure agreement as a condition of employment on this project. RTI maintains restricted access to all data preparation areas (i.e., receipt and coding). All data files on multi-user systems will be under the control of a database manager, with access to the data restricted to only project staff specifically authorized to work on this project. Survey responses are written in real-time directly to GfK/Ipsos' server and are then stored in a local Oracle database. GfK/Ipsos has developed a secure transmission and collection protocol, including the use of system passwords, encryptions, and firewalls to prevent unauthorized access to the data collection system. Individual identifying information will be maintained separately from completed questionnaires and from computerized data files used for analysis. Individual identifying information is only stored for purposes of administering survey incentives and no respondent identifiers will be contained in data to RTI or reports to CDC and results will only present data in aggregate.

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

IRB Approval

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

Sensitive Questions

The majority of questions asked will not be of a sensitive nature. There will be no requests for a respondent's Social Security Number (SSN) or other personal identification numbers. However, it will be necessary to ask some questions that may be considered to be of a sensitive nature in order to assess specific health behaviors, such as cigarette smoking. These questions are essential to the objectives of this information collection. Questions about messages concerning lifestyle (e.g., messages about smoking, current smoking behavior, attempts to quit smoking) and some demographic information, such as race/ethnicity and income, could be considered sensitive—but not highly sensitive. To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards. The informed consent process (see English and Spanish versions in **Attachments C-1** and **C-2**, respectively) will apprise respondents that these topics will be covered during the survey. This study includes a number of procedures and methodological characteristics that will minimize potential negative reactions to these types of questions, including:

- Respondents will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer.
- Web surveys are entirely self-administered and maximize respondent privacy without the need to verbalize responses.
- Participants will be provided with a specific toll-free phone number (linking directly
 to the RTI Institutional Review Board Office) to call in case there is a question or
 concern about the sensitive issue.

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

12. Estimates of Annualized Burden Hours and Costs

Information will be collected through online surveys involving adult smokers and nonsmokers in the United States, ages 18 years and older. Three survey instruments will be used: a screening & consent questionnaire (see English and Spanish versions in **Attachments C-1** and **C-2**, respectively); a survey for smokers (see English and Spanish versions in **Attachments D-1** and **D-2**, respectively); and a survey for nonsmokers (see English and Spanish versions in **Attachments E-1** and **E-2**, respectively). A total of 3 information collections per year will be

conducted over the 3-year approval period yielding a total of 9 waves of survey data (Waves A-I). Information will be collected in English and Spanish.

We will recruit an estimated 8,000 smokers for Wave A and anticipate that approximately 5,000 (63%) of those will participate in the Wave B follow-up. We anticipate maintaining a total smoker sample size of approximately 5,000 per wave through continued follow-ups and sample replenishment at each of the remaining waves (Waves C-I). Approximately 3,300 nonsmokers will be recruited for the Wave A survey and we anticipate that 2,500 (75%) of those will be retained for the Wave B follow-up. A sample of approximately 2,500 nonsmokers will be maintained through continued follow-ups and sample replenishment at each remaining wave (Waves C-I) (see Attachment J). The estimated follow-up retention and estimated replenishment rates are based on retention rate data from the longitudinal cohort used to evaluate previous campaign implementations. Panel attrition determines how much replenishment sample is needed over time versus re-contacts in order to maintain the wave-by-wave targets for sample size. We anticipate that approximately 50,000 (16,667 annualized) individuals will be screened over the 3-year data collection period to yield initial and replenishment samples. CDC has examined diagnostic data from previous similar survey projects and estimates that the burden per response is 5 minutes for the screening questionnaire and 20 minutes for the primary survey instrument. We anticipate that approximately 3% of all responses will be completed in Spanish. Although respondents may participate in multiple survey waves (e.g., Wave A, Wave B) via longitudinal follow-up, information collection will be limited to 1 response per respondent within each survey wave. That is, a single respondent cannot participate more than once in a given survey wave.

CDC currently plans to field identical instruments in all survey waves during the period of this evaluation project. However, we recognize that the relevant product market for cigarettes and other forms of tobacco and nicotine and the media environment is very dynamic. It may be necessary to make adjustments to the instrument(s) during 2020-2023 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) if this is determined to be needed.

The annual response burden during this period is estimated at 9,308 hours combined for English and Spanish versions of each survey. The total response burden is estimated at 27,924 hours over a 3-year clearance period. Burden hours for each information collection form were calculated by multiplying the total number of responses by the average burden per response. **Table A.12.1** provides details about how response burden was calculated. The Web self-administered surveys will be designed to maximize ease of response (at home on personal computers) and thus minimize respondent burden.

Table A.12.1. Estimated Annualized Burden Hours

(Type of)			Number of		
Respondents			Responses	Average	
	Form Name	Number	per Respondent	Burden per	Total

		of Respondents		Response (in Hours)	Burden (in Hours)
	Screening &			(======================================	
	Consent (English)	16,167	1	5/60	1,347
General	Screening &	,			1,5 17
Population	Consent (Spanish)	500	1	5/60	42
Adult Smokers,	Smoker Survey				
ages 18-54, in	Wave A (English)	2,587	1	20/60	862
the United States	Smoker Survey				
	Wave A (Spanish)	80	1	20/60	27
	Smoker Survey				
	Wave B (English)	1,617	1	20/60	539
	Smoker Survey				
	Wave B (Spanish)	50	1	20/60	17
	Smoker Survey				
	Wave C (English)	1,617	1	20/60	539
	Smoker Survey				
	Wave C (Spanish)	50	1	20/60	17
	Smoker Survey				
	Wave D (English)	1,617	1	20/60	539
	Smoker Survey				
	Wave D (Spanish)	50	1	20/60	17
	Smoker Survey				
	Wave E (English)	1,617	1	20/60	539
	Smoker Survey				
	Wave E (Spanish)	50	1	20/60	17
	Smoker Survey				
	Wave F (English)	1,617	1	20/60	539
	Smoker Survey				
	Wave F (Spanish)	50	1	20/60	17
	Smoker Survey				
	Wave G (English)	1,617	1	20/60	539
	Smoker Survey				
	Wave G (Spanish)	50	1	20/60	17
	Smoker Survey	_			
	Wave H (English)	1,617	1	20/60	539
	Smoker Survey	50	1	20/60	17
	Wave H (Spanish)				

	Smoker Survey				
	Wave I (English)	1,617	1	20/60	539
	Smoker Survey				333
	Wave I (Spanish)	50	1	20/60	17
Adult	Nonsmoker Survey				
Nonsmokers,	Wave A (English)	1,000	1	20/60	333
ages 18-54, in	Nonsmoker Survey				
the United States	Wave A (Spanish)	100	1	20/60	33
	Nonsmoker Survey				
	Wave B (English)	808	1	20/60	269
	Nonsmoker Survey				
	Wave B (Spanish)	25	1	20/60	8
	Nonsmoker Survey				
	Wave C (English)	808	1	20/60	269
	Nonsmoker Survey				
	Wave C (Spanish)	25	1	20/60	8
	Nonsmoker Survey				
	Wave D (English)	808	1	20/60	269
	Nonsmoker Survey				
	Wave D (Spanish)	25	1	20/60	8
	Nonsmoker Survey				
	Wave E (English)	808	1	20/60	269
	Nonsmoker Survey				
	Wave E (Spanish)	25	1	20/60	8
	Nonsmoker Survey				
	Wave F (English)	808	1	20/60	269
	Nonsmoker Survey				
	Wave F (Spanish)	25	1	20/60	8
	Nonsmoker Survey				
	Wave G (English)	808	1	20/60	269
	Nonsmoker Survey				
	Wave G (Spanish)	25	1	20/60	8
	Nonsmoker Survey				
	Wave H (English)	808	1	20/60	269
	Nonsmoker Survey				
	Wave H (Spanish)	25	1	20/60	8
	Nonsmoker Survey				
	Wave I (English)	808	1	20/60	269
	Nonsmoker Survey	25	1	20/60	8

Wave I (Spanish)				
	Total		9,308	

A.12.b Cost Burden to Respondents

Respondents participate on a purely voluntary basis and there are no start-up or maintenance costs. According to the U.S. Department of Labor (DOL) Bureau of Labor Statistics as of December 2018, the national average hourly wage is \$27.48 (DOL, 2018). Thus assuming an average hourly wage of \$27.48, the estimated annualized cost to participants will be \$255,786. The estimated value of respondents' time for participating in the information collection is summarized in **Table A.12.2**.

Table A.12.2. Estimated One-Year Annualized Cost

(Type of)		Number	Total Burden	Hourly	Total
Respondents	Form Name	of Respondents	(in Hours)	Wage Rate	Cost
	Screening &				
	Consent (English)	16,167	1,347	\$27.48	\$37,016
General	Screening &				
Population	Consent (Spanish)	500	42	\$27.48	\$1,154
Adult Smokers,	Smoker Survey				
ages 18-54, in	Wave A (English)	2,587	862	\$27.48	\$23,688
the United States	Smoker Survey				
	Wave A (Spanish)	80	27	\$27.48	\$742
	Smoker Survey				
	Wave B (English)	1,617	539	\$27.48	\$14,812
	Smoker Survey				
	Wave B (Spanish)	50	17	\$27.48	\$467
	Smoker Survey				
	Wave C (English)	1,617	539	\$27.48	\$14,812
	Smoker Survey				·
	Wave C (Spanish)	50	17	\$27.48	\$467
	Smoker Survey				·
	Wave D (English)	1,617	539	\$27.48	\$14,812
	Smoker Survey				, , , , , , , , , , , , , , , , , , ,
	Wave D (Spanish)	50	17	\$27.48	\$467
	Smoker Survey	1,617	539	\$27.48	\$14,812
	Wave E (English)				

	Smoker Survey				
	Wave E (Spanish)	50	17	\$27.48	\$467
	Smoker Survey				
	Wave F (English)	1,617	539	\$27.48	\$14,812
	Smoker Survey				
	Wave F (Spanish)	50	17	\$27.48	\$467
	Smoker Survey				
	Wave G (English)	1,617	539	\$27.48	\$14,812
	Smoker Survey				
	Wave G (Spanish)	50	17	\$27.48	\$467
	Smoker Survey				
	Wave H (English)	1,617	539	\$27.48	\$14,812
	Smoker Survey				
	Wave H (Spanish)	50	17	\$27.48	\$467
	Smoker Survey				
	Wave I (English)	1,617	539	\$27.48	\$14,812
	Smoker Survey				
	Wave I (Spanish)	50	17	\$27.48	\$467
Adult	Nonsmoker Survey				
Nonsmokers,	Wave A (English)	1,000	333	\$27.48	\$9,151
ages 18-54, in	Nonsmoker Survey				·
the United States	Wave A (Spanish)	100	33	\$27.48	\$907
	Nonsmoker Survey				
	Wave B (English)	808	269	\$27.48	\$7,392
	Nonsmoker Survey				
	Wave B (Spanish)	25	8	\$27.48	\$220
	Nonsmoker Survey				
	Wave C (English)	808	269	\$27.48	\$7,392
	Nonsmoker Survey				
	Wave C (Spanish)	25	8	\$27.48	\$220
	Nonsmoker Survey				
	Wave D (English)	808	269	\$27.48	\$7,392
	Nonsmoker Survey				
	Wave D (Spanish)	25	8	\$27.48	\$220
	Nonsmoker Survey				
	Wave E (English)	808	269	\$27.48	\$7,392
	Nonsmoker Survey				
	Wave E (Spanish)	25	8	\$27.48	\$220
	Nonsmoker Survey	808	269	\$27.48	\$7,392

Wave F (English)				
Nonsmoker Survey				
Wave F (Spanish)	25	8	\$27.48	\$220
Nonsmoker Survey				
Wave G (English)	808	269	\$27.48	\$7,392
Nonsmoker Survey				
Wave G (Spanish)	25	8	\$27.48	\$220
Nonsmoker Survey				
Wave H (English)	808	269	\$27.48	\$7,392
Nonsmoker Survey				
Wave H (Spanish)	25	8	\$27.48	\$220
Nonsmoker Survey				
Wave I (English)	808	269	\$27.48	\$7,392
Nonsmoker Survey				
Wave I (Spanish)	25	8	\$27.48	\$220
Total				\$255,786

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

There will be no respondent capital and maintenance costs.

14. Annualized Cost to the Government

This information collection is funded through a contract with RTI International. The total estimated costs attributable to this data collection are approximately \$10,500,000 from February 2020 to February 2023. 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; review of survey protocols by RTI's IRB; and progress reporting and project management. This information collection will occur from 2020 to 2023. Thus, the annualized cost to the Federal government is estimated to be \$3,530,745 (\$3,500,000 RTI cost + \$30,745 CDC cost). Two CDC health communications specialists are responsible for overseeing the content of this information collection, overall project management, and coordination with other CDC activities. The estimated cost of this information collection is summarized in **Table A.14.1**.

Table A.14.1. Itemized Cost to the Federal Government

CDC Staff Member	Annual Salary	% Allocation (Annualized)	Cost (Annualized)
GS-13	\$100,081	25%	\$25,020

GS-14	\$114,505	5%	\$5,725
		Subtotal, CDC Personnel	\$30,745
Contractual Costs for Data Collection and Management (RTI)		Subtotal, Contractual Costs	\$3,500,000
		Total Annual Cost	\$3,530,745

15. Explanation for Program Changes or Adjustments

This is being submitted as a revision of a previously approved information collection. Revisions to the survey instruments are enumerated in **Attachments D-3** and **E-3**.

There are also changes in the total estimated annualized number of responses and the total estimated annualized burden hours. While there are increases in the total number of data collection waves (due to this ICR being a three year request rather than two as previously requested and approved), there are reductions in sample sizes as well as minutes per response in each wave. These changes result in an overall net decrease in estimated annualized burden hours. The previous approval (which was for 2 years) was based on 5 waves of information collection (A-E) and this current request is based on 9 waves of information collection (Waves A-I). The average response time for each survey has been reduced from 30 minutes to 20 minutes and overall sample sizes for smokers have been reduced by approximately 1/3 to account for current market costs of data collection. In addition, total response and burden are annualized over a 3-year period whereas responses and burden were annualized over a 2-year period in the previously-approved ICR (see OMB No. 0920-1083, exp. 2/29/2020). These adjustments result in a decrease of the total annualized burden hours from 18,583 to 9,308, a net change of approximately 9,275 annualized burden hours. Details are provided in the table below.

Information	Respondents			Burden Hours		
Collection	Previous Approval	Current Request	Change	Previous Approval	Current Request	Change
Screening	25,000	16,667	-8,333	2,083	1,389	-694
Wave A Smoker	6,500	2,667	-3,833	3,250	889	-2,361
Wave B Smoker	4,000	1,667	-2,333	2,000	556	-1,444
Wave C Smoker	4,000	1,667	-2,333	2,000	556	-1,444
Wave D Smoker	4,000	1,667	-2,333	2,000	556	-1,444

Wave E Smoker	4,000	1,667	-2,333	2,000	556	-1,444
Wave F Smoker	0	1,667	1,667	0	556	556
Wave G Smoker	0	1,667	1,667	0	556	556
Wave H Smoker	0	1,667	1,667	0	556	556
Wave I Smoker	0	1,667	1,667	0	556	556
Wave A Nonsmoker	2,500	1,100	-1,400	1,250	366	-884
Wave B Nonsmoker	2,000	833	-1,167	1,000	277	-723
Wave C Nonsmoker	2,000	833	-1,167	1,000	277	-723
Wave D Nonsmoker	2,000	833	-1,167	1,000	277	-723
Wave E Nonsmoker	2,000	833	-1,167	1,000	277	-723
Wave F Nonsmoker	0	833	833	0	277	277
Wave G Nonsmoker	0	833	833	0	277	277
Wave H Nonsmoker	0	833	833	0	277	277
Wave I Nonsmoker	0	833	833	0	277	277
Total	58,000	40,434	-17,566	18,583	9,308	-9,275

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 Tips among a geographically and demographically varied population of smokers and nonsmokers in the United States. These estimates will take the form of self-reported ad recognition and recall that assess exposure to and frequency of ad exposure. These estimates will also be calculated separately for each specific advertisement. Data from this information collection will also be used to examine statistical associations between exposure to Tips and changes in specific outcomes of interest including the prevalence of quit attempts; consumption of cigarettes and other tobacco and nicotine products among smokers; knowledge, attitudes, and beliefs related to smoking; and nonsmokers' referrals of friends and family who smoke to cessation services. As noted elsewhere in this information collection request, national estimates of changes in these outcomes will be derived from the ABS-sourced samples of smokers and nonsmokers. The combined ABS and KnowledgePanel samples of smokers and nonsmokers will be utilized to generate more detailed estimates of these outcomes among smaller subgroups of interest, including those by race/ethnicity, income, education, and other characteristics. This is necessary to assess quit behavior patterns and potential aides and barriers to quitting among subgroups. See **Table A.16.1** for an example of how we will present data on exposure to campaign ads by demographic characteristics of smokers and nonsmokers.

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

	Campaign Awareness Rate, by Year [95% CI]
--	---

Smoker Subpopulation	2020	2021	2022
	XX.X%	XX.X%	XX.X%
Overall ($n = X, XXX$)	[XX.X - XX.X]	[XX.X - XX.X]	[XX.X - XX.X]
	XX.X%	XX.X%	XX.X%
Ages 18-44 (n = X,XXX)	[XX.X - XX.X]	[XX.X - XX.X]	[XX.X - XX.X]
	XX.X%	XX.X%	XX.X%
Ages 45 and older $(n = X,XXX)$	[XX.X - XX.X]	[XX.X - XX.X]	[XX.X - XX.X]
	XX.X%	XX.X%	XX.X%
Male $(n = X, XXX)$	[XX.X - XX.X]	[XX.X - XX.X]	[XX.X - XX.X]
	XX.X%	XX.X%	XX.X%
Female ($n = X,XXX$)	[XX.X - XX.X]	[XX.X - XX.X]	[XX.X - XX.X]
	XX.X%	XX.X%	XX.X%
White, Non-Hispanic ($n = X,XXX$)	[XX.X - XX.X]	[XX.X - XX.X]	[XX.X - XX.X]
	XX.X%	XX.X%	XX.X%
Black, Non-Hispanic ($n = X,XXX$)	[XX.X - XX.X]	[XX.X - XX.X]	[XX.X - XX.X]
	XX.X%	XX.X%	XX.X%
Hispanic ($n = X, XXX$)	[XX.X - XX.X]	[XX.X - XX.X]	[XX.X - XX.X]
	XX.X%	XX.X%	XX.X%
Other, Non-Hispanic ($n = X,XXX$)	[XX.X - XX.X]	[XX.X - XX.X]	[XX.X - XX.X]

Analysis of the relationship between exposure to *Tips* 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 *Tips* and changes in outcomes. These models will generally take the form of logistic (or logit) regressions for dichotomous outcomes and ordinary least squares (OLS) regressions for any continuous outcomes that are measured. To account for within-person correlations among respondents who participate in multiple survey waves, all analyses will be clustered on individual IDs using appropriate general estimating procedures. Individual IDs are randomly generated numbers that are used to identify each survey observation.

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

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

2020 C	Campaign	2021 Ca	mpaign	2022 Ca	mpaign
Pre-	Post-	Pre-	Post-	Pre-	Post-

	Campaign	Campaign	Campaign	Campaign	Campaign	Campaign
	XX.X%	XX.X%	XX.X%	XX.X%	XX.X%	XX.X%
Incidence of	[XX.X-	[XX.X-	[XX.X-	[XX.X-	[XX.X-	[XX.X-
Outcome	XX.X]	XX.X]	XX.X]	XX.X]	XX.X]	XX.X]
Odds Ratio	X.	XX	Χ.Σ	ΧX	Χ.Σ	ΧX
for Post-	[XX.X	-XX.X]	[XX.X –	·XX.X]	[XX.X -	- XX.X]
Campaign	(P <x.xx)< td=""><td>(P<x< td=""><td>.XX)</td><td>(P<x< td=""><td>.XX)</td></x<></td></x<></td></x.xx)<>		(P <x< td=""><td>.XX)</td><td>(P<x< td=""><td>.XX)</td></x<></td></x<>	.XX)	(P <x< td=""><td>.XX)</td></x<>	.XX)
Model N	Χ,Σ	XXX	X,X	XX	X,X	XX

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

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

The reporting and dissemination mechanism will consist of three primary components: (1) summary statistics (in the form of PowerPoint presentations and other briefings) on individual awareness of and reactions to *Tips*; (2) a comprehensive evaluation report summarizing findings from this information collection; and (3) at least three peer-reviewed journal articles that document the relationships between Campaign exposure and changes in the aforementioned outcomes of interest. Given the data limitations noted in this ICR, all interpretation and reporting of evaluation results will be made with reasonable caution and will appropriately acknowledge these limitations. OMB approval is requested by January 2020 or as soon as possible to facilitate timely launch of data collection. The project time schedule is summarized in **Table A.16.1.**

Table A.16.1 Project Time Schedule

Project Activity	Time Schedule	
Wave A smoker and nonsmoker data collection	1 month within OMB approval	
Wave B smoker and nonsmoker data collection	4 – 6 months after OMB approval	
Wave C smoker and nonsmoker data collection	7 – 9 months after OMB approval	

Wave D smoker and nonsmoker data collection	12 – 13 months after OMB approval
Wave E smoker and nonsmoker data collection	14 – 16 months after OMB approval
Wave F smoker and nonsmoker data collection	17 – 19 months after OMB approval
Wave G smoker and nonsmoker data collection	24 – 26 months after OMB approval
Wave H smoker and nonsmoker data collection	27 – 29 months after OMB approval
Wave I smoker and nonsmoker data collection	30 – 32 months after OMB approval
Preparation of analytic data file	32 – 34 months after OMB approval
Data analysis	34-36 months after OMB approval
Report writing and dissemination	34-36 months after OMB approval

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

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

- Abreu, D.A., & Winters, F. (1999). *Using monetary incentives to reduce attrition in the survey of income and program participation*. Proceedings of the Survey Research Methods Section of the American Statistical Association.
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- Southwell, B.G., Barmada, C.H., Hornik, R.C., & Maklan, D.M. (2002). Can we measure encoded exposure? Validation evidence from a national campaign. *Journal of Health Communication*, *7*(5), 445-453.