

Information Collection Request

New

**National Tobacco Education Campaign**

**Rough-Cut Testing of Television, Radio, Print, and Digital Advertisements**

(OMB No. 0920-0910)

**Supporting Statement: Part A**

**Program Official/Contact**

Michelle O'Hegarty, PhD

Office on Smoking and Health

National Center for Chronic Disease Prevention and Health Promotion

Centers for Disease Control and Prevention

4770 Buford Highway, NE MS F-79

Atlanta, Georgia 30341

770-488-5582

FAX: 770-488-5939

Email: [mohegarty@cdc.gov](mailto:mohegarty@cdc.gov)

May 7, 2019

## TABLE OF CONTENTS

### A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary
2. Purpose and Use of Information Collection
3. Use of Improved Information Technology and Burden Reduction
4. Efforts to Identify Duplication and Use of Similar Information
5. Impact on Small Businesses or Other Small Entities
6. Consequences of Collecting the Information Less Frequently
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
8. Comments in Response to the Federal Register Notice & Efforts to Consult Outside Agency
9. Explanation of Any Payment or Gift to Respondents
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents
11. Institutional Review Board (IRB) and Justification for Sensitive Questions
12. Estimates of Annualized Burden Hours and Costs
13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers
14. Annualized Cost to the Federal Government
15. Explanation for Program Changes or Adjustments
16. Plans for Tabulation and Publication and Project Time Schedule
17. Reason(s) Display of OMB Expiration Date is Inappropriate
18. Exceptions to Certification for Paperwork Reduction Act Submissions

### LIST OF ATTACHMENTS

Attachment 1: Online Questionnaire Email Invitation to Potential Respondents

Attachment 2: Online Questionnaire Recruitment Screener

Attachment 3: Online Questionnaire

Attachment 4: Online Questionnaire Main Screenshots

Attachment 5: Toluna Terms and Conditions

Attachment 6: Battelle Institutional Review Board Approval

Attachment 7: Toluna Privacy Policy

**Notes on Excluded Attachments.** In this information collection request (ICR), CDC outlines a plan to test rough-cut advertisements (ads) with content that may be considered sensitive. The draft materials are not included because the near-final, “rough-cut” ads have not been approved for public distribution by HHS/Assistant Secretary for Public Affairs (ASPA). To support adequate review of this Gen IC by OMB, the Centers for Disease Control and Prevention requests permission to provide OMB with a secure link to the draft materials.

## Supporting Statement: Summary

- **Goal of the Proposed Project:** The goal of this proposed project is to test reactions to 10 rough-cut ads in television, radio, print, and digital formats designed to encourage people who smoke to quit. These ads will illustrate the harmful effects that smoking-related diseases, such as heart disease, Buerger's disease, and chronic obstructive pulmonary disease, have on the people who used to smoke as well as the family. Rough-cut ads are near-final versions of ads with unedited photos, placeholder voiceovers, etc. The resulting information will be used to refine the rough-cut ads to develop into final ads for a future *Tips From Former Smokers*<sup>®</sup> (*Tips*<sup>®</sup>) campaign.
- **Intended use of the resulting data:** Once collected data is analyzed, the results will yield information to produce clear, credible, believable, and effective ads to motivate people who smoke to quit smoking conventional cigarettes completely.
- **Methods to be used to collect data:** Quantitative methods will be used to collect data on 10 ads. Ads will be tested in 4 formats (television, radio, print, and digital). There will be a total of 10 ads or 10 tests. Quantitative data will be collected through online surveys (which include a screener and a questionnaire) of 20,116 respondents, 16,000 of which are expected to view ads and complete the questionnaire. The survey will collect information about the participants' reactions to the rough-cut ads as well as basic demographic and tobacco use information to understand whether and how these factors may influence individuals' responses to these messages.
- **Populations to be studied:** The population will be adults who smoke cigarettes and adults who don't smoke, aged 18-54 years.
- **How data will be analyzed:** The resulting data will be analyzed using statistical techniques for quantitative data. Data will be analyzed using aggregate measures such as percentages and means. Analyses will focus on whether participants' evaluations of ad clarity, credibility, believability, and effectiveness differ across ads. Additionally, data from open-ended questions (e.g., about the main message of the ad) will be analyzed qualitatively using thematic analysis.

## Part A. Justification for Information Collection

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

While significant improvements have been made in reducing the smoking rate in the United States since the first Surgeon General's Report came out more than 50 years ago, cigarette smoking is still the leading cause of preventable disease and death in the United States, accounting for more than 480,000 deaths every year, or one of every five deaths (U.S. Department of Health and Human Services (HHS), 2014). In addition, more than 16 million Americans live with a smoking-related disease (HHS, 2014). In 2018, the prevalence of cigarette smoking among adults was 13.7% (Creamer et al., 2019). In March 2012, the Centers for Disease Control and Prevention (CDC) launched the first-ever paid national tobacco education campaign—*Tips From Former Smokers*® (*Tips*®)<sup>1</sup>. The *Tips*® campaign profiles real people who are living with serious long-term health effects from smoking and secondhand smoke exposure. The primary audience is adults who smoke, ages 18 through 54. Secondary audiences include family members, health care providers, and faith communities. The goals of the *Tips*® campaign are to:

- Build public awareness of the immediate health damage caused by smoking and exposure to secondhand smoke;
- Encourage people who smoke to quit, and let them know that free help is available; and
- Encourage people who smoke not to smoke around others and encourage people who don't smoke to protect themselves and their families from exposure to secondhand smoke.

To date, the *Tips*® campaign has had a significant impact on cessation behaviors among U.S. adults who smoke over time because of the continued use of graphic, hard-hitting, emotional ads (Davis, Patel, Shafer et al., 2017). During 2012–2018, the campaign was associated with approximately one million sustained quits among U.S. adults who smoke, and more than 16.4 million quit attempts (Murphy-Hoefer, Davis, King, Rodes, & Beistle, 2019). The *Tips*® campaign has also been associated with increased knowledge of tobacco-related health risks (Huang, Thrasher, Abad et al., 2015.) In addition, during the first year of the campaign, an estimated 6 million people who don't smoke talked with friends and family about the dangers of smoking. Furthermore, economic analysis of the campaign has shown that for every \$2,000 we spend on the ads, we prevent a death (CDC, 2019). More information about the impact of the campaign can be found at [cdc.gov/tipsimpact](http://cdc.gov/tipsimpact).

Given that more than 480,000 Americans still die every year, it is important to continue a national tobacco education campaign that motivates people who smoke to try to quit and lets them know that free resources are available to help them if needed. Standard accepted advertising practices include developing new ads in order to continue to motivate the audience to change their behavior. Some of the ads have been used every year since the 2012 launch. CDC, in collaboration with their contractor, The Plowshare Group, and subcontractors, Qualtrics and Battelle, will test a set of rough-cut TV, radio, print, and digital ads for a future *Tips*® campaign media buy.

---

<sup>1</sup> Use of trade names is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

Rough-cut testing is a standard advertising research activity used in the development of communication campaigns and is the step that immediately precedes the development of final ads. Rough-cut testing is crucial to ensuring that the ad informs the target audience of the health consequences caused by smoking cigarettes and motivates them to act (e.g., quit smoking cigarettes or talk to a loved one about the dangers of smoking cigarettes). Additionally, rough-cut testing is a way to measure any unanticipated confusion, ambiguity, or lack of understanding of the ad's message.

The objective of the proposed project is to test rough-cut television, radio, print, and digital ads among adults who smoke and adults who don't smoke, ages 18-54. The content in these ads is derived from the life experiences of adults who used to smoke cigarettes and their family members. Ads will be tested in 4 formats (television, radio, print, and digital). There will be a total of 10 ads or 10 tests.

Information gleaned from subpopulation analyses will inform ad development and communication channels. Ad reactions will be analyzed with the full sample, as well as between and within several subpopulations defined by smoking status, socioeconomic status (SES), and age. People who smoke will be classified as either low-SES or non-low-SES based on education, employment status, and income. Participants will be classified as low-SES people who smoke if they meet criteria for people who smoke and at least two of the following three criteria:

- Have a high school education or less, or completed high school without further schooling;
- Have a household income in 2019 of less than \$25,000; and/or
- Are currently unemployed (excluding retirees and the disabled).

Age group and SES subpopulation analyses are important to the analysis plan; they will be used to prioritize ad development and communication channels. The subpopulations of interest are as follows:

- Young adults who smoke (18-26 years of age)
- Young adults who do not smoke (18-26 years of age)
- Older adults who smoke (27-54 years of age)
- Older adults who do not smoke (27-54 years of age)
- Low-SES adults who smoke (18-54 years of age)
- Non-low-SES who smoke (18-54 years of age)

Stratified sampling will be used to reach subpopulation recruitment goals while minimizing the number of respondents required. Recruitment targets by strata for people who smoke and people who don't smoke are detailed in **Table A.1** and **Table A.2**.

Age group: 18-26 SES group: Low	Age group: 18-26 SES group: Non-low	Age group: 27-54 SES group: Low	Age group: 27-54 SES group: Non-low
200	200	200	200

\* Recruitment goal per ad: 400 respondents ages 18-26 and 400 respondents ages 27-54

Table A.2 Recruitment Targets for Each Ad: People Who Do Not Smoke*	
Age group: 18-26	Age group: 27-54
400	400

\*Recruitment goal per ad: 800 respondents ages 18-54

In order to assess how the rough-cut ads are perceived across a number of measures, including perceived effectiveness (PE) (Davis, Duke, Shafer et al., 2017), believability, comprehension, and emotional reactions, approximately 16,000 respondents will view and react to rough-cut ads that focus on the harmful effects that smoking-related diseases, such as heart disease, Buerger’s disease and chronic obstructive pulmonary disease have on people who used to smoke, as well as the family.<sup>2</sup> Of these, 400 respondents from each subpopulation of people who smoke and 400 respondents from each subpopulation of people who don’t smoke will view each of the 10 ads. Recruitment for each stratum will close when that stratum is filled. The maximum number of respondents for each ad is 1,600 (800 + 800) and the maximum number of respondents for all ads is 16,000 (1,600 x 10). **Section A.12** and **Part B** includes additional information on sample size calculations.

**A.2 Purpose and Use of Information Collection**

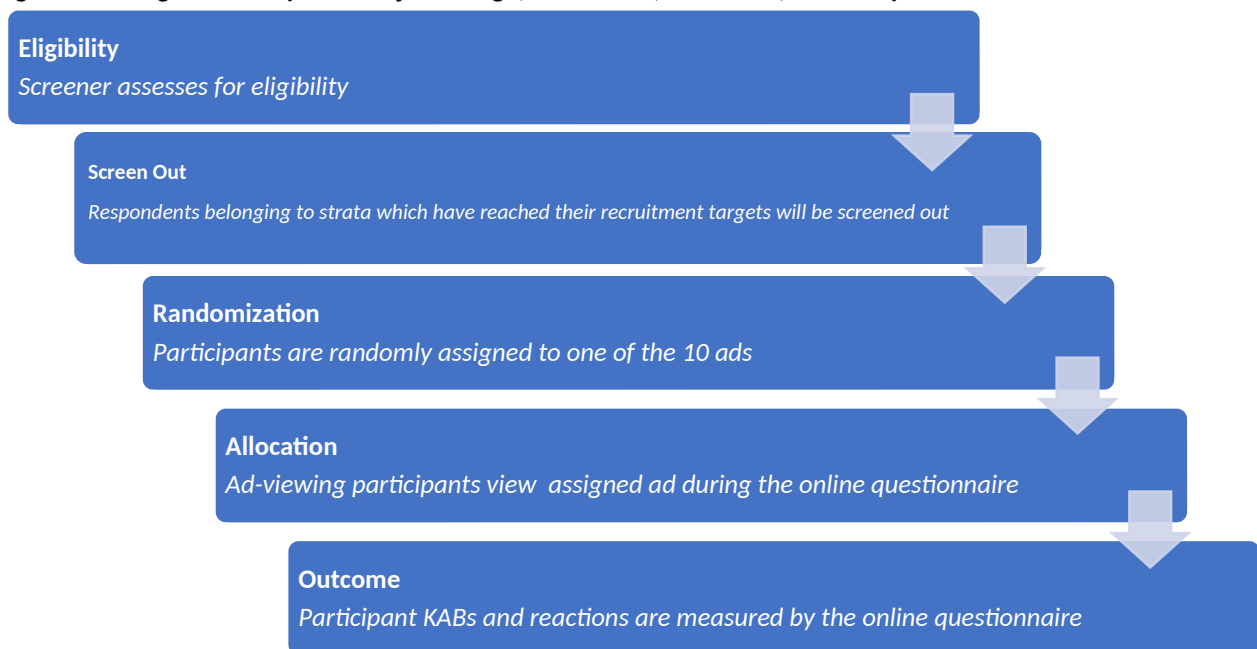
This proposed project is part of a collection of ICRs submitted under a dedicated generic clearance to develop campaign ads. Previous ICRs approved under this generic clearance to assist with ad development include message platform testing, creative concept testing, and rough-cut testing. For example, the program received OMB approval to test 2020 rough-cut ads on July 29, 2019 (OMB No. 0920-0910). The ads tested in July 2019 – September 2019 will air as part of the 2020 *Tips*<sup>®</sup> campaign. The rough-cut ads that test well with the target audience in the proposed project will be used as part of a future *Tips*<sup>®</sup> campaign. If this information collection is not performed, CDC will not know whether these rough-cut ads communicate credibly and effectively with the target audience. This could result in the production of ads that are not effective in encouraging people who smoke to quit.

Potential participants will be recruited from an existing, online, convenience panel managed by Toluna (see <https://us.toluna.com/#/> for more detail on this panel). The panel provider maintains demographic information about panelists in its proprietary database, which is not released (see Toluna Privacy Policy, Attachment 7), and this information will be used to ensure that the invitation to participate in this project (Attachment 1) will target only individuals who are likely to be eligible. An online, project-specific screener (Attachment 2) will be used to confirm respondents’ age, state of residency, level of education, income, employment status and tobacco use behavior.

<sup>2</sup> To achieve this final sample size, it is anticipated that the total number of respondents who need to initiate the screener is 20,116 accounting for attrition. More detail on how this number was calculated this is included in **Section A.12**.

Following the screening process, eligible respondents will complete the online questionnaire (Attachment 3). The purpose of the online questionnaire is to show respondents the rough-cut ads. The questionnaire will measure demographic characteristics, tobacco use behaviors and perceptions, and reactions to the ads (e.g., PE, confusion, believability, emotional response, effect on motivation to quit smoking, etc.). Respondents will be randomized to one of the 10 rough-cut ads being tested (meaning, each respondent will see or hear only one ad). Randomization of respondents ensures that there is a similar distribution of individuals with different measured and unmeasured characteristics across ads. Overall, this is designed to have high internal validity even though external validity (i.e., generalizability) is low because of the volunteer sample. The project design is summarized in **Figure A.1** and key variables are summarized in **Table A.3**.

**Figure A.1. Diagram of Proposed Project Design, Enrollment, Allocation, and Analyses**



**Table A.3. Key Variables**

Table A.3. Key Variables		
<b>Screener</b>	<b>Inclusion Criteria</b>	
	Age	DAGE2
	State of Residency	DEMO2
	SES (Education; Income; Employment)	SES1; SES2; SES3
<b>Questionnaire</b>	Tobacco Use Status	TS1; TS2; TS3
	<b>Demographic and Psychographic Variables</b>	
	Demographics (Gender; Race/Ethnicity)	DEMO1; DEMO3; DEMO4
	Awareness of tobacco advertising campaigns	P8; P9; P10; P11
	<b>E-Cigarette Variables</b>	
	E-cigarette behavior	E1; E2; E3
	<b>Tobacco Variables</b>	
	Tobacco Use Status/Behaviors	TS1a; TS1b; TS2
	Quit Attempts	QA1; QA2; QA30; QA4; QA5; QA102
	Tobacco Attitudes and Beliefs	P5a; P5b1; P5b2; P5d; D210; D211
	<b>Outcome Variables</b>	
Ad Reactions	M1; M2; H1; H2; RC5a; RC5b; M3; M4; M5a; M5b; M6a; M7b; M8a; M600; RC14; RC15; RC16; RC17; RC14b; RC31	

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

During data collection, all information (from the screener and the questionnaire) will be collected electronically utilizing an integrated Web-based software platform (see Attachment 4). Web-based surveys are an especially convenient option for eliciting feedback on visual, audio, and textual stimuli such as the rough-cut ads to be tested. The use of a web-based platform also offers a number of benefits for managing the quantitative data collection:

- First, use of an existing online panel will allow CDC to obtain information quickly so that needed adjustments to health messaging can be made expeditiously and campaign development can progress rapidly from planning to implementation. The panel used for this testing is very large (more than 1.7 million people in the U.S.), allowing quick selection of participants from extremely small subgroups of the population. Samples from this panel are not designed to generate nationally representative samples or precise population parameters but rather are used as a highly efficient, low cost, and low



burden method of data collection for formative rough-cut testing.

- Second, when a respondent enters the screener for this project, the link to his or her identifiable information is severed (i.e., the link to the identifiable information maintained by the panel provider). None of the information collected through screening or the online questionnaire is identifiable, providing a secure environment for participants.
- Third, this technology permits participants to complete the instruments in private. Providing the participant with a methodology that improves privacy makes reporting of potentially embarrassing or stigmatizing behaviors (e.g., tobacco use) less threatening and enhances response validity and response rates.
- Finally, the web-based software system includes embedded logic that will route respondents efficiently through the screener and onto the online questionnaire (or a “thank you” screen, if the respondent is found to be ineligible). This approach can increase participation rates (which decreases time and costs related to information collection procedures) by reducing the number of respondents needed to complete the screener in order to achieve the desired enrolled sample size (i.e., by reducing drop off between the screener and questionnaire).

Overall, the software supports an efficient assignment and routing process, as well as a smooth user experience that would be difficult to attain in other modes of data collection.

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

The U.S. Department of Health and Human Service’s Office of the Assistant Secretary for Planning and Evaluation (ASPE) has reviewed this proposed collection of information and has determined that it does not duplicate other collections. To prepare for data collection, CDC reviewed existing published literature, and unpublished qualitative pretesting reports (e.g., the findings from previous formative testing) when they were available.

CDC collaborates with other federal government agencies that sponsor or endorse health communication projects, such as FDA’s Center for Tobacco Products (CTP). Staff members in CDC’s Office on Smoking and Health work closely with staff in CTP’s Office of Health Communication and Education. Regularly scheduled conference calls are held to review plans and share research findings of mutual interest. These collaborations serve as information channels, help prevent redundancy, and promote use of consistent measures of effectiveness. Coordination activities include the review of data collection instruments and other support materials for testing purposes.

FDA CTP is investing in a number of public education campaigns aimed at youth and young adults, such as *The Real Cost*, *Fresh Empire*, and *This Free Life* to educate them about the dangers of regulated tobacco products.

CDC continues to share findings from its information collection efforts with CTP to ensure that message and campaign development is complementary and not duplicative.

Points of contact for this coordination are:

- CDC: Brian Armour, Associate Director for Science, Office of the Associate Director for Science, telephone (404) 498-3014, email [bka9@cdc.gov](mailto:bka9@cdc.gov)
- CDC: Elizabeth Courtney-Long, Health Scientist, Office of the Associate Director for Science, telephone (404-498-0264), email [gmr9@cdc.gov](mailto:gmr9@cdc.gov)
- CDC: Diane Beistle, Chief, Health Communications Branch, telephone (770) 488-5066, email [zgv1@cdc.gov](mailto:zgv1@cdc.gov)
- CDC: Lindsey McCarter, Team Lead, Campaign Development, Health Communications Branch, telephone (770) 488-4239, email [lpq4@cdc.gov](mailto:lpq4@cdc.gov)
- CDC: Michelle O'Hegarty, Health Communications Specialist, Campaign Development, Health Communications Branch, telephone (770) 488-5582, email [mohegarty@cdc.gov](mailto:mohegarty@cdc.gov)
- FDA: Matthew Walker, Lead Health Scientist, Office of Health Communication and Education, telephone (240) 402-3824, email [matthew.walker@fda.hhs.gov](mailto:matthew.walker@fda.hhs.gov)
- FDA: Tesfa Alexander, Center for Tobacco Products, telephone (301) 796-7745, email [Tesfa.Alexander@fda.hhs.gov](mailto:Tesfa.Alexander@fda.hhs.gov)
- FDA: Chaunetta Jones, FDA, Center for Tobacco Products, telephone (240) 402-0427, email [Chaunetta.Jones@fda.hhs.gov](mailto:Chaunetta.Jones@fda.hhs.gov)
- FDA: Janine Delahanty, FDA, Center for Tobacco Products, telephone: (240) 402-9705, email: [Janine.Delahanty@fda.hhs.gov](mailto:Janine.Delahanty@fda.hhs.gov)

#### **A.5 Impact on Small Business or Other Small Entities**

This data collection will not involve small businesses or other small entities.

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

This is a one-time information collection request.

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

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

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

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

A Notice was published in the Federal Register on December 13, 2017, volume 82, number 238, pp. 58609-58611. No public comments about this data collection were received by CDC.

##### **A.8.b Consultations**

The *Tips*<sup>o</sup> campaign has been funded primarily with funds from the Affordable Care Act/Public Health Fund designated for smoking education since 2010. CDC did not consult outside of the agency on the rough-cut ads.

#### **A.9 Explanation of Any Payments or Gift to Respondents**

Participants will be drawn from the established Toluna panel system, which provides points to panelists to encourage participation (see Attachment 5: Toluna's Terms and Conditions). Immediately upon completion of the survey, each respondent will be provided with points equivalent to \$0.50. These points are accrued with other points when the panelist takes part in other surveys through the Toluna panel system. At any time, the panelist can redeem their points for different products, such as gift cards. Studies have indicated that a monetary gift can increase response rates (Church, 1993; Greenbaum, 2000; Haveman, 2010).

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

This submission has been reviewed by staff in CDC's National Center for Chronic Disease Prevention and Health Promotion, who determined that the Privacy Act does not apply. This determination is based on the fact no personal identifiers will be collected in this proposed project to reduce the likelihood of identification or re-identification. CDC has contracted with The PlowShare Group for this information collection and The PlowShare Group's data collection and formative research subcontractors are Qualtrics and Battelle. All data collected and delivered to CDC from The PlowShare Group's data collection and formative research subcontractors will be in aggregate form only. Further, the information that will be reported to and maintained by CDC is not considered a record as defined by the Privacy Act: it will not include individuals' education, financial transactions, medical history, and criminal or employment history and name, or the identifying number, symbol, or other identifier assigned to any individual, such as a finger or voice print or a photograph. Staff from CDC, Qualtrics, and Battelle participated in planning the information collection; staff from each will interpret data but will not receive any Personally Identifiable Information (PII) on the respondents. Battelle's Institutional Review Board (IRB) reviewed this project and determined it to be exempt (Attachment 6). The IRB's primary concern is protecting respondents' rights, one of which is maintaining the privacy of participant information to the fullest extent of the law.

#### Privacy and Confidentiality of Online Questionnaire System

All information for the self-administered screening process and self-administered questionnaire will be collected electronically in a secure, web-based data collection system (as described in Section A2 and Part B). The identifiable information about Toluna panelists is maintained in a proprietary records system and is not released to CDC or other contractors/subcontractors (see Attachment 7: Toluna Privacy Policy). Although demographic information (e.g., age, state of residency, socioeconomic status) and tobacco use status will be confirmed through screening, no direct personal identifiers (e.g., date of birth [including day, month, year], name, phone number, address, email address, social security number, photograph, biometric information, or any other unique identifier that can be linked to an individual) will be collected or maintained as part of the Screener or Questionnaire (Attachments 2 and 3). A system of records notice (SORN) is not required because (1) the information collected is not considered a record as defined by the Privacy Act and (2) the records are not retrieved using a personal identifier.

When the respondent begins the questionnaire, all identifiable links to the existing system of

records are severed. As such, because it does not exist, CDC will not have direct contact with or access to any PII about participants during this stage. Toluna does have access to the email address of panel subscribers, but no match back is possible with the survey response data. IP addresses will not be stored by the online questionnaire system, and no first- or third-party cookies will be stored during questionnaire completion. No link between the respondent's email and the specific survey is made after the potential respondent clicks on the link to start the survey.

#### Data Security

All findings will be reported in aggregate form only. All information will be stored on password-protected databases to which only Qualtrics employees working on this project have access. Qualtrics will keep the quantitative data in non-aggregate form for six months after information collection has been completed, and then the respondent-level data will be deleted from the password-protected databases. Qualtrics will provide CDC and Battelle with the de-identified data, to be used for analyses. Only CDC, Qualtrics, and Battelle employees involved in data analysis will have access to the data. CDC will handle the de-identified data in accordance with the record control schedule (maintained at least six years, but no longer than ten years). No desktop or laptop computer will contain any PII. To prevent unauthorized access to their data servers (such as "hacking"), Qualtrics is currently certified and has achieved the distinguished ISO 27001 accreditation. With this achievement, Qualtrics' data systems have assurance that all data will be managed in a secure environment. This means that Qualtrics has been formally audited and has been certified compliant with the standard ISO 27001 accreditation. CDC will retain and destroy records in accordance with the applicable CDC Records Control Schedule (**Table A.4.**).

<b>Technical Controls</b>	<b>Physical Controls</b>	<b>Administrative Controls</b>
<ul style="list-style-type: none"> <li>• User identification</li> <li>• Passwords</li> <li>• Firewall</li> <li>• Virtual Private Network (VPN)</li> </ul>	<ul style="list-style-type: none"> <li>• Guards/Security Officers</li> <li>• 24-hour maintenance of Video/Audio of all data centers and all offices</li> <li>• Identification badges</li> <li>• Key Cards</li> </ul>	<ol style="list-style-type: none"> <li>1. The system security plan for the information collection is that survey data and all identifying information about respondents will be handled in ways that prevent unauthorized access at any point during the proposed project.</li> <li>2. The contingency plan for this information collection is that the screeners will be kept only on password-protected computer files stored on a Qualtrics server. No directly identifying information will be transmitted to CDC (thus, the Privacy Act does not apply).</li> <li>3. Backup file storage: Qualtrics has a redundancy system stored on a FedRAMP-certified server farm for data security and quality. Reports will not include any identifiable information.</li> <li>4. There will not be user manuals for this information collection effort.</li> <li>5. Personnel who use the system will be trained to protect the information being collected and maintained by adhering to a procedure that removes identifiers from response data.</li> <li>6. Contractors who are operating/using the system will include clauses in the contracts that adhere to privacy provisions and practices.</li> <li>7. Methods will be in place to ensure least privilege. Data and all identifying information about respondents will be handled in ways that prevent unauthorized access at any point during the proposed project.</li> <li>8. There are policies/guidelines in place regarding the retention and destruction of PII: PII will not be transmitted to CDC, and PII will not be linked to response data.</li> </ol>

## **A.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. Battelle’s IRB has reviewed this proposed project and determined it to be exempt (Attachment 6).

### Sensitive Questions

The majority of questions asked in the Online Questionnaire Recruitment Screener (Attachment 2) and Online Questionnaire (Attachment 3) will not be of a sensitive nature. There will be no requests for a respondent’s Social Security Number (SSN). Questions asked during the screening about tobacco use and some demographic information (e.g., age) could be considered sensitive, although these items would not generally be considered highly sensitive. It will also be necessary to ask some questions considered to be sensitive in order to assess individuals’ attitudes and behaviors about tobacco products and to test ads about the specific health behavior of cigarette smoking. These items are not generally considered highly sensitive either. Participants will be informed of the applicable privacy safeguards. Sensitive information

will only be requested when necessary to describe sample characteristics (e.g., age). Such questions will include a “prefer not to answer” option. This proposed project also includes a number of procedures and methodological characteristics that will minimize potential negative reactions to potentially sensitive questions, including the following:

- The online questionnaire is entirely self-administered and maximizes participant privacy by being conducted online, without the need to verbalize responses.
- Participants will be provided with a phone number and email for the principal investigator and for the IRB, should they have any questions or concerns about the proposed project or their rights as a participant.

#### **A.12 Estimates of Annualized Burden Hours and Costs**

The 10 rough-cut ads will be tested with approximately 16,000 respondents. As described in **Section A.1**, each rough-cut ad will be tested with approximately 1,600 respondents for each ad. Each rough-cut ad will be viewed or listened to by approximately 800 people who smoke and 800 people who don't smoke.

To obtain this sample size, approximately 20,116 respondents are anticipated to initiate the online screener (Attachment 2); this estimate is based on two factors from prior experiences in the field. First, it is anticipated that roughly 18 percent of screener respondents (n=3,621) will be deemed ineligible for the proposed project because of not meeting inclusion criteria. Second, of those deemed eligible (n=16,495), an estimated three percent (n=495) will start but not complete the questionnaire. Thus, 20,116 respondents are needed to obtain the sample size of 16,000.

The burden per respondent for completing the screener is two minutes. The total estimated burden for respondents who complete the screener (N=20,116) is 671 hours. The burden per respondent for completing the online questionnaire is 13 minutes. The total estimated burden for those who complete the questionnaire (n=16,000) is 3,467 hours. Those who start but do not complete the questionnaire are estimated to spend about one-half of that time (7 minutes) on the questionnaire. Thus, the total estimated burden for those who start but do not complete the online questionnaire (n=495) is 58 hours. As outlined in **Table A.5.**, the total estimated burden for the entire project is 4,196 hours.

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Adult who smoke and adults who don't smoke who are ages 18-54	Online Recruitment Screener (Attachment 2)	20,116	1	2/60	671
	Online Questionnaire (Attachment 3)	16,000	1	13/60	3,467
		495	1	7/60	58
<b>Total</b>					<b>4,196</b>

The estimated cost of the time devoted to this information collection by respondents is \$104,816.08 as summarized in **Table A.6**. To calculate this cost, we used the mean hourly wage of \$24.98, which represents the Department of Labor estimated mean for state, local, and private industry earnings (Bureau of Labor Statistics, 2018). There are no direct costs to respondents associated with participation in this information collection.

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)	Hour Wage Rate	Total Cost
Adults who smoke and adults who don't smoke who are ages 18-54	Online Recruitment Screener (Attachment 2)	20,116	1	2/60	671	\$24.98	\$16,761.58
	Online Questionnaire (Attachment 3)	16,000	1	13/60	3,467	\$24.98	\$86,605.66
		495	1	7/60	58	\$24.98	\$1,448.84
<b>Total</b>							<b>\$104,816.08</b>

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

There will be no respondent capital and maintenance costs.

### **A.14 Annualized Cost to the Government**

Approximately 6.25% of one full-time equivalent (FTE) and 1.9% of one senior manager will be required to oversee the information collection activities for one month. Responsibilities will include internal coordination and review of materials and reports and maintaining proper accounting of burden hours. The agency estimates that it will take a GS-13, at a wage rate of \$58.10/hour, approximately 10 hours to manage the project, totaling about \$581.00. It is estimated to take a GS-15, at a wage rate of \$68.34/hour, approximately three hours to oversee the total project, totaling \$205.00. The total average annualized cost to the government for CDC oversight is \$786.

Contractors will conduct the majority of information collection and management activities on CDC’s behalf. The total cost of the data collection contractors is \$97,000 which includes consultation, instrument design and development, respondent incentives, data collection and analysis, and final report. Qualtrics will collect the information from the participants. Activities are coordinated through a contract with The PlowShare Group, a specialist in media campaigns. The grand total cost for the project, including government and contractor cost, is \$97,786.

<b>Table A.7. Total Project Costs</b>				
<b>Government Personnel</b>	<b>Percent Time Commitment</b>	<b>Hour Time Commitment</b>	<b>Hourly Basic Rate</b>	<b>Total</b>
GS-13	6.25%	10	\$58.10	\$581
GS-15	1.9%	3	\$68.34	\$205
<b>Subtotal, Government Personnel</b>				\$786
<b>Contract Costs</b>				\$97,000
<b>Total Costs</b>				\$97,786

**A.15 Explanation for Program Changes or Adjustments**

This is a new data collection.

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

Data Tabulation Plans

The information will be used to inform the development of final ads for a future *Tips*® campaign. It is anticipated that information collection will begin May 6, 2020 so an OMB approval date of May 5, 2020 is requested. The resulting quantitative data will be analyzed using conventional tabulation techniques. These dates may be adjusted depending on the approval process of this package.

Publication and Dissemination Plans

These ads will be aired as part of future media buys. Additionally, a comprehensive formative evaluation report summarizing findings from this information collection will be provided to CDC.



## Project Time Schedule

**Table A.8 Project Time Schedule**

<b>Table A.8. Project Time Schedule</b>	
<b>Activity</b>	<b>Time Schedule</b>
Email invitations sent to respondents for quantitative testing	1-30 days after OMB approval
Online data collection	1-30 days after OMB approval
Complete field work	30-45 days after OMB approval
Validation	45-55 days after OMB approval
Data analysis	55-65 days after OMB approval
Report writing	65-150 days after OMB approval

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

An exemption to this requirement is not being requested. The expiration date of OMB approval will be displayed on all information collection instruments.

### **A.18 Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

## References

- Bureau of Labor Statistics. (2018). *May 2018 National Occupational Employment and Wage Estimates - United States*. Retrieved from [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)
- Centers for Disease Control and Prevention. (2019). *Tips From Former Smokers® : Tips® Impact and Results*. Retrieved November 25, 2019 from <https://www.cdc.gov/tobacco/campaign/tips/about/impact/campaign-impact-results.html>
- Church, A. H. (1993). Estimating the effect of incentives on mail survey response rates: A meta-analysis. *Public opinion quarterly*, 57(1), 62-79.
- Creamer, M.R., Wang, T.W., Babb, S., Cullen, K.A., Day, H., Willis, G. ... Neff, L. (2019). Tobacco Product Use and Cessation Indicators Among Adults — United States, 2018. *Morbidity and Mortality Weekly Report*, 68(45), 1013-1019.
- Davis, K. C., Duke, J., Shafer, P., Patel, D., Rodes, R., & Beistle, D. (2017). Perceived effectiveness of antismoking ads and association with quit attempts among smokers: Evidence from the Tips From Former Smokers campaign. *Health communication*, 32(8), 931-938.
- Davis, K.C., Patel, D., Shafer, P., Duke, J., Glover-Kudon, R., Ridgeway, W., & Cox, S. (2017). Association between media doses of the *Tips From Former Smokers* campaign and cessation behaviors and intentions to quit among cigarette smokers, 2012-2015. *Health Education & Behavior*, 1-9.
- Department of Health and Human Services (HHS). (2014). *The Health Consequences of Smoking — 50 Years of Progress: A Report of the Surgeon General*. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.
- Greenbaum, R. T. (2000). *Selecting the right site: Where do states locate place-based economic development programs?* Paper presented at the Proceedings. Annual Conference on Taxation and Minutes of the Annual Meeting of the National Tax Association.
- Haveman, R. H. (2010). Principles to guide the development of population health incentives. *Prev Chronic Dis*, 7(5), A94.
- Huang, L.L., Thrasher, J.F., Abad, E.N., Cummings, K.M., Bansal-Travers, M. Brown, A., Nagelhout, G.E. (2015). The U.S. national Tips From Former Smokers antismoking campaign: Promoting awareness of smoking-related risks, cessation resources, and cessation behaviors. *Health Education & Behavior*, 42, 480-486.
- Murphy-Hoefer, R., Davis, K., King, B.A., Rodes, R., Beistle, D. (2019). Over half a million quits & going strong: How the *Tips®* campaign continues to help smokers quit smoking for good. National Conference on Tobacco or Health, Minneapolis, MN, August 27-29, 2019 (poster session).