Message Testing for Tobacco Communication Activities (MTTCA)

Request for Revision (OMB No. 0920-0910, exp. 1/31/2015)

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Supporting Statement: Part A

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

In 2012, CDC's Office on Smoking and Health obtained OMB approval of a generic clearance that established a unified information collection framework for the development of tobacco-related health messages, including messages related to the ACA-funded tobacco education campaign (Message Testing for Tobacco Communication Activities (MTTCA), OMB No. 0920-0910, exp. 1/31/2015). Since that time, CDC has employed the MTTCA clearance to collect information about smokers' and nonsmokers' attitudes and perceptions, and to pre-test draft messages and materials for clarity, salience, appeal, and persuasiveness. A variety of information collection strategies are supported through this mechanism, including in-depth interviews, in-person focus groups, online focus groups, computer-assisted, in-person, or telephone interviews, and online surveys. CDC requests OMB approval for each data collection by submitting an Information Collection Request that describes project purpose, use, and methodology.

The MTTCA clearance was initially approved with the following estimates: 5,775 annualized burden hours and 14,974 annualized responses. On January 2, 2014, CDC obtained OMB approval of a revision to the MTTCA clearance to increase the annualized number of responses to 36,847 and the estimated annualized burden hours to 7,219.

This is a three-year renewal request to the 0920-0910 MTTCA clearance to encompass the proposed activities. We added additional capacity to account for unanticipated future activities. We are requesting a 20% increase in the estimated annualized number of responses and a 52% increase in burden hours starting on the current expiration date of January 31, 2015. The new estimated annualized number of responses is 44,216 and the estimated annualized burden hours are 10,998.

CDC will continue to use the MTTCA clearance to develop and test messages and materials for current and future phases of the ACA-funded media campaign, as well as OSH's ongoing programmatic initiatives including, but not limited to, the Media Campaign Resource Center, reports from the Office of the Surgeon General, and other communication efforts and materials. The MTTCA generic clearance may also be used to facilitate the development of tobacco-related health communications of interest for CDC collaborative efforts with other federal partners including, but not limited to, the Food and Drug Administration, the Substance Abuse and Mental Health Services Administration, the National Institutes of Health, and the National Cancer Institute. The MTTCA clearance is sufficient to test tobacco related messages developed by CDC. However, this should not replace the need for additional generic clearance mechanisms HHS and other federal partners may need to test tobacco messages related to their campaigns and initiatives.

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

Tobacco use remains the leading preventable cause of death in the United States. The primary mission of the Health Communications Branch (HCB) of the Office on Smoking and Health (OSH) at the Centers for Disease Control and Prevention (CDC) is to serve as a public health resource for tobacco and health information. Through the Health Communications Branch, OSH develops and distributes information about tobacco and health to the public, professionals, various branches of government, and other interested groups nationwide using a wide array of formats and media channels. OSH also maintains a reference library of tobacco-related communication materials, called the Media Campaign Resource Center (MCRC), and provides technical assistance to organizations so that MCRC materials can be customized for specific media applications. CDC is authorized to conduct information collection supporting these activities under the Public Health Service Act (41USC 241) Section 301 (see Attachment 1a). OSH also collaborates closely on an ongoing basis with the Food and Drug Administration's Center for Tobacco Products (CTP). Since 2009, the FDA has gained broad authority to regulate tobacco product advertising through the Family Smoking Prevention and Tobacco Control Act.

Recent legislative developments highlight the importance of tobacco control--and appropriate tobacco control messages--in efforts to improve the nation's health. These developments include the Affordable Care Act (ACA), which established the Prevention and Public Health Fund (PPHF). The PPHF contains essential disease prevention initiatives to help reduce the health and financial burden of tobacco use, such as increasing the number of insured individuals; improving the overall availability of effective cessation treatments; expanding coverage benefits for smoking-cessation treatments; and creating a new prevention trust fund for proven prevention, wellness, and public health efforts. The PPHF specifically calls for the implementation of a national, science-based media campaign to increase awareness of the health consequences of tobacco use and exposure to secondhand smoke.

CDC's Office on Smoking and Health is tasked with planning, fielding, and evaluating the ACA-funded media campaign, which includes health messages for the target audience (adults ages 18-54 years old) and a number of messages that are tailored to specific audience segments (e.g., smokers versus nonsmokers). Adolescents are a secondary target audience for the ACA-funded media campaign. CDC's hard-hitting media campaigns encourage quitting and reduce smoking. The campaign is and will be delivered through a variety of media channels and formats, including television ads, radio ads, digital ads and print materials.

Among the changes that are being considered in this request to extend 0920-0910 is an expansion of the target audience to include youth ages 13-17 years old. There may be a need to test prevention and cessation messages related to products that are not currently regulated, including non-combustible tobacco products (electronic nicotine delivery systems such as electronic cigarettes or e-cigarettes) and some combustible products (e.g. cigars/little cigars and cigarillos). In the event that FDA receives authority to regulate these products and decides to

do a campaign about them, CDC would work closely with FDA to avoid duplication. Additionally, CDC will share with FDA the findings from any formative work related to the youth audience.

The 2014 Surgeon General's Report concluded that there is already sufficient evidence to caution youth against the use of electronic cigarettes. Tobacco and electronic cigarette advertising and promotional activities can prompt smoking initiation, especially among youth. Recent studies have found that 90.7% of middle school students and 92.9% of high school students have been exposed to pro-tobacco advertisements in stores, magazines and on the internet. Media campaigns have been shown to be effective as part of a comprehensive tobacco control program to decrease the initiation of tobacco use among youths and young adults. A coordinated series of health message testing activities will be required to support future development of effective, audience-specific and channel-specific messages for CDC's ACA-funded tobacco prevention and control campaign.

In addition, successful campaign management will include companion assessment and evaluation activities that are closely coordinated with initial message development and execution. Information collection for campaign assessment and evaluation activities has been approved in a separate but related Information Collection Request (OMB No. 0920-0923, exp. 03/31/2017, Evaluation of the National Tobacco Prevention and Control Public Education Campaign).

HCB uses established standards of health communication planning as depicted in the figure below, which begins with **1) Planning and Strategy Development**. This step can occur via formal needs assessments with partners and intended users (i.e., the target audience) and a review of published literature and epidemiological data related to a specific health problem. A needs assessment can be accomplished by conducting surveys, for example, to determine pressing health needs or concerns of the target audience. Next, HCB must understand a target audience's current behaviors, beliefs, attitudes, and knowledge about tobacco-related issues to effectively design health messages, programs, and campaigns. This information can be gained with focus groups, interviews, and/or surveys. These will guide selection and application of behavioral theories to a program's strategies and messages and audience segmentation. [1,2,3]
2) Developing and Pretesting Concepts, Messages, and Materials. In this second step, HCB designs draft messages that must be tested with members of the target audience. [4, 5] Audience feedback, in the form of interviews, focus groups or surveys, is incorporated into subsequent

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1 Fishbein, M. & Yzer. 2003. Using Theory to Design Effective Health Behavior Interventions. *Communication Theory*, 13(2), 164-183

2 Thackeray & Neiger. 2000. Establishing a Relationship Between Behavior Change Theory and Social Marketing. *Journal of Health Education*, 31(6), 331-335.

3 Noar, S. 2006. A 10-Year Retrospective of Research in Health Mass Media Campaigns. *Journal of Health Communication*, 11, 21-42.

4 Andreasen, A. 1995. *Marketing Social Change*. San Francisco, Jossey-Bass.

5 Black, D.R., Blue, C.L., & Coster, D.C. (2001) Using social marketing to develop and test tailored messages. *American Journal of Health Behavior, 25(3)*: 260-271.

revisions. Audience testing informs the final development of messages, materials or advertisements and is essential for ensuring that federal dollars are expended appropriately on health messages that are effective. **3) Implementing the Program.** HCB implements the program and conducts process evaluation to ascertain to what extent the program was implemented as planned and under what conditions. This information can directly feed information back into the program for improvement. **4) Assessing Effectiveness and Making Refinements**. HCB must conduct outcome evaluation of the program components to assess the degree to which the program was effective. This process also captures lessons learned for improving subsequent iterations of the program and for similar future efforts.

To support the time-critical ACA-funded media campaign, as well as additional tobacco-related health communications to be conducted by HCB, CDC obtained OMB approval January 2, 2014 of a revision of the current generic clearance for the development of tobacco-related health messages and campaigns (OMB No. 0920-0910, exp. 1/31/2015). The MTTCA generic clearance is founded on a strategic and systematic approach to the design and testing of high-quality health messages, campaigns, and programs, and employs accepted methods of health message development, including input from public health partners, and pre-testing with target audiences. (Figure 1).[6,7]

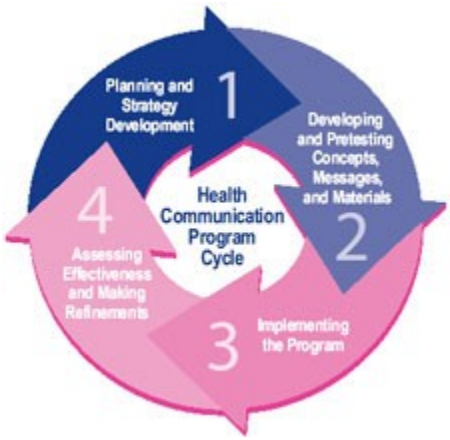

Figure 1. Health Communication Program Cycle. From: National Cancer Institute, National Institutes of Health. (2008). Making Health Communication Programs Work. http://www.cancer.gov/cancertopics/cancerlibrary/pinkbook (accessed June 22, 2011).

The generic MTTCA clearance provides a unified clearance framework for a variety of tobacco-related communication activities primarily related to steps 1-3 described above, which may occur on an as-needed basis, or in the context of a planned series utilizing a variety of methodologies. A generic clearance is needed to support the breadth, flexibility and time-sensitivity of information collection required to develop materials to be used in the upcoming

6 (National Cancer Institute, 2008, *Making Health Communication Programs Work*, http://www.cancer.gov/cancertopics/cancerlibrary/pinkbook).

7 Roper, W.L. 1993. Health Communication Takes on New Dimensions at CDC. *Public Health Reports*, 108(2), 179-183.

ACA-funded tobacco communication campaign, OSH's ongoing programmatic initiatives, and the Surgeon General's reports. **Attachment 3** provides an overview of projected program needs during the time period of January 31, 2015 through January 31, 2018, including estimated burden to respondents.

At this time, CDC is submitting a three-year revision request to the 0920-0910 MTTCA clearance to increase the estimated responses and the annualized estimated burden hours starting on the current expiration date of January 31, 2015. The new estimated annualized number of responses is 44,216 and the new estimated annualized burden hours are 10,998. The purpose of increasing the annualized responses and burden hours is to account for planned future activities. Our experience with the activities performed under this generic clearance has demonstrated that some needs are not foreseen at the time of the initial submission and our current request will provide the flexibility to accommodate future activities. The increases will be used for short, medium and in-depth surveys which are in line with activities proposed in the current generic clearance.

OSH will request OMB approval for each data collection activity through submission of a specific Information Collection Request that describes its purpose, use, methodology, and impact on affected respondents. Given that every data collection instrument will be based upon specific data collection needs for different stages of health communication planning and implementation, it is not possible to develop one instrument for use in all instances. **Attachment 4** provides illustrative examples of questions that could be asked for a variety of information collections.

A.2. Purposes and Use of Information Collection

The primary purpose and use of information collection under MTTCA will be to inform the development and testing of materials for CDC's ongoing ACA-funded tobacco prevention and control campaign. In the initial generic clearance period, we outlined the following purposes and uses of information to be collected. We plan to continue using the MTTCA clearance in these ways:

- Inform the health communication efforts related to release of Surgeon General Reports.
- Provide critical knowledge about specific target audiences for tobacco communication activities conducted by OSH and tobacco control collaborators.
- Understand influences on individuals' attitudes, knowledge and beliefs around tobacco use and quitting behaviors and how this may influence perception of messages
- Ensure that HCB designs and provides relevant and timely health communication technical assistance to partners as a result of ongoing needs assessments.
- Develop and refine message concepts and test draft materials for clarity, salience, appeal, and persuasiveness to target audiences.
- Ensure quality and prevent waste in the dissemination of health information by

CDC/HCB to the public.
- Assess the effectiveness of produced campaign materials in communicating with target audiences.
- Allow for the collection of health and other employment-specific information from individuals who apply to be spokespersons for the campaign.

Formative pretesting is a standard best practice in communications research for creating messages for target audiences that are credible, comprehensible and persuasive. The results of message testing intended for a specific audience or context may inform future programs designed for similar situations.

Since approval of MTTCA in January 2012, this mechanism has been used to support creative concept testing, rough cut testing of television, print, digital ads and radio ads for the ACA-funded media campaign. In addition, MTTCA has been used to facilitate information collection from women about their perceptions of risk relating to smokeless tobacco products and nicotine replacement therapy.

The following new items are requested in this proposed Revision ICR:
- Expansion of the target audience to include youth ages 13-17 who may be a subpopulation of interest for future activities such as message testing.
- Extend the duration of the generic clearance for three years.
- Increase the number of annualized responses and burden hours to account for planned activities and to allow for flexibility for future activities.

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

Whenever possible and appropriate, information collections submitted for approval under this generic clearance will use advanced technology to collect and process data in order to reduce respondent burden and to make data processing and reporting maximally efficient. Particular emphasis will be placed on compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII (Attachment 2c). As computer technology has continued to improve and become more widespread, opportunities to pretest messages on the Internet using either Web-based surveys or on-line focus groups have increased. Using computer-assisted information technology to transmit data collection instruments and/or collect responses will continue to reduce the burden on respondents. Wherever possible, CDC/HCB will make use of Web-based data collection methods. Further, in all message, concept, material, and ad testing, the number of questions will be held to the absolute minimum required for the intended use of the data and trained interviews and moderators will lead the discussions, where appropriate, to ensure that time is used in the most efficient and productive manner. Following are examples of the types of technology that may be used to reduce burden; evolving technologies may also be employed.

Online Interviews, Focus Groups, Bulletin Boards and Surveys:

A Web-enabled panel approach uses online technology to collect data from households that participate in an ongoing panel. The panels are very large, allowing quick selection from the overall pool and the rapid identification of several potential respondents from extremely small subgroups of the population. Samples from these panels 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 message testing. A Web-enabled or online panel approach also allows for the immediate turnaround of transcripts from online focus groups and data from online surveys.

Online methods for focus groups, bulletin boards and surveys can minimize burden because they can be completed in the respondent's home or workplace, at the respondent's convenience and, in some cases, do not require the presence of an interviewer. They are less burdensome than mailed questionnaires in that they eliminate the need to handle and return paper copies.[8]
For online bulletin boards, respondents can respond to a pre-loaded discussion guide at their own convenience while a trained live moderator monitors responses throughout the duration of the bulletin board. Web-based surveys are an especially convenient option for eliciting feedback on visual stimuli. With Web-based surveys, respondents view an ad, complete an online survey and then submit the data electronically and securely over the Internet. Online methods for bulletin boards and surveys are described in more detail in Part B. Relative to less technically advanced methods, these data collection approaches have the advantages of speed, cost, access and reduced burden.

Other Surveys:
Some surveys will be conducted via mail, or emergent technologies, similar to that described in the previous section. However, other surveys will be conducted by telephone and will consist of quantitative closed-ended questions. When most interview items response alternatives are "closed ended," as in a survey, a Computer-Assisted Telephone Interview (CATI) will be utilized to help phone interviewers move quickly and accurately through items and skip patterns, reducing response burden.

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

Prior to conducting any data collection, CDC reviews existing published literature and unpublished qualitative pretesting reports when they are available, and also consults with outside experts to identify information that could facilitate message development. Health messages developed by CDC/HCB are unique in their mix of intended audience, health behavior, concept, and execution. Therefore, there are no similar data available.

CDC/HCB collaborates with other U.S. government agencies that sponsor or endorse health communication projects, such as the FDA's Center for Tobacco Products. These collaborations

8 Stempel, G.H., Stewart, R.K. (2000) The internet provides both opportunities and challenges for mass communication researchers. *Journalism and Mass Communication Quarterly*, *77(3):*541-548.

serve as information channels and help prevent redundancy. CDC and FDA are coordinating and collaborating closely on tobacco information collections and material development to avoid duplication of efforts and to support each other's campaign messaging. CDC will ensure that commonalities on measures for youth will be used wherever possible. Relevant communications will be documented in each information collection request submitted to OMB for approval under the MTTCA generic clearance.

Specifically, the CDC's Office on Smoking and Health, FDA's Center for Tobacco Products, the National Institute for Health, the National Cancer Institute and the Substance Abuse and Mental Health Services Administration are working with the Office of the Assistant Secretary for Planning and Evaluation to coordinate data collection efforts in the area of tobacco information, and steps have been made to harmonize data elements and outcome measures, as well as to eliminate duplication of effort across the area of tobacco information collection. CDC is participating in the HHS Tobacco Data Work Group to improve coordination and collaboration of tobacco-related data collection activities across the Department. This coordination includes, for example, shared topical areas such as cessation behavior, perceptions of health risk, health status, as well as all others. Coordination activities include questionnaire review and item re-use where at all possible. OSH/HCB has coordinated with FDA through monthly calls to review plans and weekly regarding campaign coordination with their Health Communication and Education staff. OSH/HCB has also shared this revision package with FDA staff as well as findings from CDC's ACA funded media campaign (e.g. Rough Cut Testing Report). OSH/HCB is currently identifying additional areas for collaboration and sharing of data with NIH, NCI and SAMHSA. We plan to share with these previously mentioned federal agencies all future findings from the formative work that will be submitted to OMB under this revised package.

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

Respondents are typically members of the general public, specific subpopulations or specific professions, not business entities. No impact on small businesses or other small entities is anticipated.

A.6. Consequences of Collecting the Information Less Frequently

In the interest of responsive and timely health communication, programs may forgo the important steps of conducting needs assessments, assessing target audience awareness, attitudes, knowledge, beliefs, and behaviors; and testing messages on dimensions such as clarity, salience, appeal, and persuasiveness (i.e., the ability to influence behavioral intention). Skipping these steps avoids delay and expense, but at a high potential cost. A program designed without a clear understanding of the issue or message from the target audience's perspective can be minimally effective, at best. Untested messages can waste communication resources and opportunities because the messages can be perceived as unclear or irrelevant.[9] Untested messages can also have unintended consequences, such as jeopardizing the credibility

9 Wallendorf, M. (2001) Literally literacy. *The Journal of Consumer Research, 27(4)*: 505-511.

of Federal health officials.[10]

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

There are no special circumstances. The message testing activities fully comply with the guidelines in 5 CFR 1320.5.

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

A.8.a. Federal Register Notice

A Federal Register Notice was published in the *Federal Register* on August 11, 2014, Vol. 79, No. 154, pp. 46829-46830 (**Attachment 2a**). One public comment was received and acknowledged (**Attachment 2b**).

A.8.b. Consultation

The Food and Drug Administration has reviewed this draft revision request to 0920-0910 as part of our ongoing coordination and collaboration on tobacco information collections.

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10 Harris-Kojetin, D., McCormack, L.A., Jael, L.A., Sangl, E.F., & Garfinkel, S.A. (2001) Creating more effective health plan quality reports for consumers: Lessons from a synthesis of quality testing. *Health Services Research, 36(3)*: 447-476.

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

Participation in certain data collections will be requested on a voluntary basis without specific incentives. However, CDC may request OMB approval to offer incentives in some circumstances, when a) respondents incur costs for participation (e.g., transportation costs) or make substantial time commitments, b) information is needed from respondents who are difficult to reach or recruit, or c) information collection is time-sensitive and recruitment must be accelerated. Each request to offer an incentive will be appropriately justified on a case-by-case basis and will describe the type of incentive to be offered (cash, gift certificate or reward "points"), and the amount. Reviewed literature reveals that the payment of incentives can provide significant advantages to the government in terms of direct cost savings and improved data quality.[11] Incentives are intended to recognize the time burden placed on study participants, encourage their cooperation, and to convey appreciation for contributing to the study.

A.10. Assurance of Confidentiality Provided to Respondents

This revision request supports continuation of an existing generic clearance. Because a variety of procedures may be used to collect information, general guidelines follow, based on the primary modes of information collection (focus groups, interviews, and Web-based surveys of existing panels conducted by contract organizations on CDC's behalf). Each project-specific data collection request submitted to OMB for review and approval will include 1) a description of the applicable privacy safeguards, 2) a project-specific Privacy Act determination, and 3) a project-specific IRB approval, if required.

A.10.1 Privacy Impact Assessment Information

Overview of the data collection system

A variety of information collection procedures, some of which are described in this document, may be implemented within the context of this generic clearance. Each request submitted for OMB approval will include a description of information collection procedures specific to the request, privacy safeguards when applicable, a Privacy Act determination, and documentation of IRB approval (when applicable), or a statement indicating that IRB approval is not required.

CDC anticipates that participation in all data collection under this generic clearance will be voluntary.

Although personal information (e.g., gender, age, and race) may be gathered for screening or in interviews and focus group-type activities to describe an audience segment, no personal identifiers (e.g., full name, address or phone number, social security number, etc.) will be collected or maintained. For online surveys, information will be collected electronically through a self-administered survey instrument hosted in a secure, online, web-based data collection system. The web-based system is ideal because of the ease of presenting visual stimuli (the advertisements) to respondents and recording their feedback. Respondents will be recruited through an existing web-based panel system, and screened for eligibility and interest prior to administration of the main information collection instrument. There is no Website content being planned that will be directed at children younger than 13 years of age. All data provided by respondents will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Respondents will be informed prior to participation that their responses will be treated in a secure manner. The CDC will not have direct contact with participants nor will have access to any personal identifying information about the panelists.

Overview of Information Collection

Online data collections will conform to federal regulations [the Hawkins-Stafford Amendments of 1988 (P.L. 100-297) and the Computer Security Act of 1987] and will be required to comply with comprehensive, written plans to maintain security. This plan will include having all personnel who will have access to individual identifiers sign non-disclosure agreements. They will also be trained in the applicable privacy safeguards, to handle requests for information from respondents, and in providing assurance to respondents about the protection of their responses.

Best practices for web-based surveys include the following: Surveys sent electronically from the Web site will be sent to an email address solely dedicated for the information collection project. The electronic surveys will be received, a record of the receipt will be made, and the survey will be separated from any identifying information, including the email address of the sender. These surveys will be forwarded to other staff for data analysis. All electronic file transmissions will be encrypted and password protected. Additional best practices include restricted access to all data preparation areas (i.e., receipt and coding). All data files on multi-user systems will be under the control of a database manager, with access limited to project staff on a “need-to-know” basis only. For all surveys, multiple security measures will be undertaken to ensure separation between respondents’ identity and their survey data. For online surveys, data coming directly from the survey engines are stored in proprietary databases. Once inside the firewall, all data are stored in a relational database protected by several layers of intrusion detection and access control. Data files delivered to the contractors by any survey vendors will be sent via encrypted files.

Overview of how information will be shared and for what purpose

Information will be collected and evaluated by CDC personnel and/or CDC's data collection contractors. CDC plans to collaborate with its data collection contractors on the survey content and will also be involved in the analysis, interpretation, and implementation of the results from the data. The CDC will not have direct contact with participants nor will CDC have access to any personal identifying information about the panelists. The data collection contactors, in collaboration with CDC, plan to analyze overall levels of effectiveness, respondent motivation, and assessed believability of the tested advertisements, controlling for potential cofounders including demographic characteristics, state of residence, smoking status, and parental status, for most surveys executed under the auspices of this generic clearance.

Overview of the impact the proposed collection will have on the respondent's privacy

Independent of the data collection system, no individually identifiable information will be collected as part of any data collection. No personal identifying information (PII) will be collected. The CDC data collection contractors will typically recruit from an existing system of records. While the CDC data collection contractors may have access to the email address of panel subscribers, no match back is possible to the panel subscribers, and no PII will be shared with CDC or any agencies. When the respondent begins the survey, all identifiable links to the existing system of records are severed. No link between the respondent email and any specific information collection will be made after the potential respondent begins the survey. No data will be collected that will tie the respondent back to the email or any other personal identifying information.

Overview of voluntary participation

Independent of the data collection system, all potential respondents will be advised of the nature of the activity, the length of time it will require, and that participation is voluntary. The appropriate advisements on voluntary participation will also be provided to respondents, generally during the recruitment, consent and/or screening process. These procedures conform to ethical practices for collecting data from human participants.

Overview of data security

Independent of the data collection system, all data will be reported in the aggregate only. All electronic data will be stored on password-protected databases on servers accessible only to CDC staff or authorized data collection contractors. No desktop or laptop computer will contain any personal identifying information. Any data collected is de-identified through use only of sample unit identifiers and cannot be traced back to any of the subjects. Neither CDC data collection contracts nor CDC employees working on the project will have access to any identifying information. CDC contractors will keep the data in non-aggregate form for six months after data collection has been completed, and then the observation-level data will be deleted from the password-protected databases.

When data are collected by means of paper questionnaires (i.e., additional individual questionnaires to complement in-person focus group data), the questionnaires will be kept in

locked filing cabinets in the offices of project staff employed by CDC contractors. When the data have been coded into electronic files and cleaned, the paper records will be destroyed. Electronic files (whether generated by touch screen technology, email or by coding paper records) will be stored in secured electronic files at a contractor's office and will be accessible only to key staff directly involved in the project who will be trained and knowledgeable in ensuring data confidentiality. In reports, all presentation of data will be in aggregate form, and no links to individuals will be preserved. Reports will not include identifiable information on respondents. A system of records will not be created under the Privacy Act, as no individually identifiable information will be collected for any data collection under this generic clearance.

A.11. Justification for Sensitive Questions

The majority of questions asked will not be of a sensitive nature. However, at times, it will be necessary to ask questions considered to be of a sensitive nature in order to assess individuals' attitudes and behaviors or test messages about a specific health behavior, such as cigarette smoking, for example. Questions about messages concerning lifestyle (e.g., messages about smoking, expectations about the personal health effects of smoking or secondhand smoke, etc.), and questions about messages related to illnesses such as cancer or cardiovascular disease could be considered sensitive. Questions about sensitive issues may be necessary for audience segmentation. To avoid fear of disclosure of sensitive information, respondents will be informed of the applicable privacy safeguards.

To avoid negative reactions to potentially sensitive questions, several steps may be taken:

- 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.
- Where possible, use of touch-screen methodology or other self-directed techniques will provide privacy; not having to verbalize a response may increase comfort.
- When such numbers are available and appropriate, participants will be provided with specific agency hotline numbers to call in case they have a question or concern about the sensitive issue.
- Interviewers will be trained to ask questions in a sensitive manner and to handle any subsequent discussion skillfully. Where appropriate, interviewers and respondents will be matched for gender and other demographic criteria (e.g., age, preferred language use).
- If specific health information is obtained from medical professionals, informed consent will be obtained

Sensitive information will only be requested when necessary for specific project objectives.

A.12. Estimated Annualized Burden Hours and Cost

Information will be collected through methods including, but not limited to,

- Screening to ensure proper selection of participants. The majority of screening activities

will average two minutes per response.

- In-depth interviews, including interviews conducted with key informants. Interviews will typically be conducted in-person with an average burden of one hour per response.
- In-person focus groups, primarily for creative concept testing; and online focus groups, primarily for social media concept testing. The estimated burden per response is 1 – 1.5 hours.
- Short surveys (average 10 minutes per survey) conducted online or through bulletin boards, for message platform testing, message validation and copy testing, rough cut testing and final revised cut testing.
- Medium-length surveys (average 25-40 minutes per survey) conducted online for quantitative social media concept testing, and validation of advertisements and Surgeon General Report materials.
- In-depth surveys (average one hour per survey) for in-depth formative testing of message concepts, etc.
- Questionnaires (average 10 minutes per application) conducted by mail, email or by telephone interview to identify individuals who may be featured in ads developed for OSH's media campaigns or materials.

The distribution of OSH's needs for information collection through screening, surveys, interviews, and focus groups may change over time. An approximate distribution is described in Table A.12.A below. The number of responses/respondents and total burden hours will be itemized in each request submitted to OMB for approval under the MTTCA generic clearance.

Table A.12.A. Estimated Annualized Burden to Respondents

Type of Respondents	Data Collection Method	Number of Respondents	Number of Responses per Respondent	Average Burden per Response	Total Burden (in hours)
General Public and Special Populations	Screening and Recruitment	20,000	1	2/60	667
	In-depth Interviews (In Person, telephone, etc.)	96	1	1	96
	Focus Groups (In Person)	160	1	1.5	240
	Focus Groups (Online)	120	1	1	120
	Short Surveys/employment application (Online, Bulletin Board, etc.)	9,800	1	10/60	1,633

	Medium Surveys (Online)	9,940	1	25/60	4,142
	In-depth Surveys (Online)	4,100	1	1	4,100
	Total	44,216			10,998

Because the time required for responding to a survey or interview, and to participate in a focus group has a monetary value, this table estimates the total annual cost to the respondents for all activities and breaks the total figure down by the principal data collection strategies that may occur over a one year period.

According to the U.S. Department of Labor (DOL) Bureau of Labor Statistics as of June 2014 the national average hourly wage is $22.33. Because of the scope of this generic clearance and the variety of the types of participants, this national average hourly wage was utilized. The total annualized burden cost is estimated at $245,586 per year.

Table A.12.B. Estimated Annualized Burden Costs

Type of Respondents	Data Collection Method	Total Burden (in hours)	Average Hourly Wage	Total Cost
	Screening and Recruitment	667	$22.33	$14,894
General Public and Special Populations	In-depth Interviews (In Person, telephone, etc.)	96	$22.33	$2,144
	Focus Groups (In Person)	240	$22.33	$5,359
	Focus Groups (Online)	120	$22.33	$2,680
	Short Surveys (Online, Bulletin Board, etc.)	1,633	$22.33	$36,465
	Medium Surveys (Online)	4,142	$22.33	$92,491
	In-depth Surveys (Online)	4,100	$22.33	$91,553
			Total	$245,586

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

There are no additional costs to respondents associated with capital, startup or recordkeeping expenses.

A.14. Estimates of Annualized Cost to the Federal Government

Approximately 25% of one full-time equivalent (FTE) and 5% of one senior manager will be required to oversee this generic clearance and associated information collection requests. Additional responsibilities will include internal coordination of a specific Information Collection Requests and maintaining proper accounting of burden hours. The total average annualized cost to the government for CDC oversight is $33,909.

The majority of data collections will be conducted by contractors on CDC's behalf. The costs of each information collection activity will be itemized in the project-specific request submitted for approval under this generic clearance.

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-13	25%	$108,299	$27,075
GS-15	5%	$136,674	$6,834
		Total	$33,909

A.15. Explanation for Program Changes or Adjustments

The changes that are being proposed in this Revision request are as follows:

- Expansion of the target audience to potentially include youth ages 13-17 years old who may be a subpopulation for future message testing activities.
- Extend the duration of the generic clearance for three years.
- Increase the number of annualized responses by 20% (from 36,847 to 44,216) and increase the estimated annualized burden hours by 52% (from 7,219 to 10,998) starting on the current expiration date of January 31, 2015 to account for planned future activities and to accommodate some unanticipated activities. Our experience has shown that some needs develop later in the generic clearance period and we need flexibility to accommodate these requests. The principal sources of increases are in the areas of short, medium, and in-depth surveys. An itemized summary of estimated changes is provided below.

	Previous Approval		Proposed Changes for Current Revision			
Data Collection Method	No. Respondents	No. Burden Hours	No. Respondents	No. Burden Hours	Increase in Respondents	Increase in Burden Hours
Screening and Recruitment	20,000	667	20,000	667	0	0
In-depth Interviews	67	67	96	96	29	29
Focus Groups (In Person)	160	240	160	240	0	0
Focus Groups (Online)	120	120	120	120	0	0
Short Surveys	6,500	1,083	9,800	1,633	3,300	550
Medium Surveys	8,500	3,542	9,940	4,142	1,440	600
In-depth Surveys	1,500	1,500	4,100	4,100	2,600	2,600
Total	36,847	7,219	44,216	10,998	7,369	3,779

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

Results of the information collections conducted under this generic clearance will be used primarily to inform programmatic efforts. Information collections conducted in Years 1-3 of the MTTCA generic clearance included cognitive interviews, message platform testing, creative

concept testing (i.e., focus groups), and rough cut testing (i.e., online surveys) related to the development of messages and materials for the ACA-funded media campaign. Results that may be of interest to health communicators may be disseminated through presentations at professional meetings and publications. Analyses of quantitative data may be estimated with sampling weights that adjust for non-response and sample design. The information will be used to inform health communication strategies across OSH. Findings from these analyses may be immediately used to help with future decision-making.

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

Not applicable. All data collection instruments will display the expiration date for OMB approval of the information collection.

A.18. Exceptions to the Certification Statement

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