**Message Testing for Tobacco Communication Activities (MTTCA)**

**(OMB No. 0920-0910, exp. 1/31/2015)**

Revision

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Supporting Statement: Part A

Centers for Disease Control and Prevention

National Center for Chronic Disease Prevention and Health Promotion

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**Abstract**

In 2012, OSH 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 non-smokers’ 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.

CDC requests OMB approval to revise the generic MTTCA clearance, which was initially approved with the following estimates: 5,775 annualized burden hours and 14,974 annualized responses. The initial estimates were based on the number of respondents who were likely to participate in information collection activities such as focus groups, interviews, and surveys. The initial estimates did not account for specific screening activities that are necessary to identify respondents from key target audiences such as subpopulations and hard-to-reach populations. As a result, the initial MTTCA clearance underestimated the total number of responses associated with information collection under the MTTCA clearance. This revision will adjust for the needed screening activities by allocating 20,000 additional responses, and 667 additional burden hours, to the previously approved annualized estimates. To accommodate both planned activities and potential new initiatives or collaborations, we are also requesting modest increases in the number of respondents and burden hours associated with survey activities.

This revision request does not affect the current expiration date of January 31, 2015. The estimated annualized number of responses will increase from 14,974 to 36,847 and the estimated annualized burden hours will increase from 5,775 to 7,219.

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, OSH’s ongoing programmatic initiatives including the Media Campaign Resource Center (MCRC) and reports from the Office of the Surgeon General, and collaborative efforts within CDC. The MTTCA generic clearance may also be used to facilitate the development of tobacco-related health communications of interest to CDC and other federal partners, including the Food and Drug Administration (FDA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the National Institutes of Health (NIH), and the National Cancer Institute (NCI).

**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 CDC/HCB, OSH develops and distributes information about tobacco and health to the public, professionals, various branches of government, and other interested groups nationwide using a wide array of formats and media channels.  OSH also maintains a reference library of tobacco-related communication materials, called the Media Campaign Resource Center (MCRC), and provides technical assistance to organizations so that MCRC materials can be customized for specific media applications. CDC is authorized to conduct information collection supporting these activities under the Public Health Service Act (41USC 241) Section 301 (see **Attachment 1a**). OSH also collaborates closely with the Center for Tobacco Research (CTR) in the Food and Drug Administration (FDA). Since 2009, the FDA has gained broad authority to regulate tobacco product advertising through the Family Smoking Prevention and Tobacco Control Act (see **Attachment 1b**).

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, see **Attachment 1c**). 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 will include 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 non-smokers). The campaign will be delivered through a variety of media channels and formats, including television ads, radio ads and print materials. A coordinated series of health message testing activities will be required to support the development of effective, audience-specific and channel-specific messages for this 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. 4/30/2014, Evaluation of the National Tobacco Prevention and Control Public Education Campaign).

To support the time-critical ACA-funded media campaign, as well as additional tobacco-related health communications to be conducted by OSH’s Health Communications Branch (HCB), CDC obtained OMB approval of a new generic clearance for the development of tobacco-related health messages and campaigns (OMB No. 0920-0910, exp. 1/31/2015, Message Testing for Tobacco Communication Activities (MTTCA)). The MTTCA generic clearance is being revised. It 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).[[1]](#footnote-2),[[2]](#footnote-3)

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, CDC/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. [[3]](#footnote-4),[[4]](#footnote-5),[[5]](#footnote-6)

**2) Developing and Pretesting Concepts, Messages, and Materials**. In this second step, CDC/HCB designs draft messages that must be tested with members of the target audience. [[6]](#footnote-7), [[7]](#footnote-8) Audience feedback, in the form of interviews, focus groups or surveys, is incorporated into subsequent 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.



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 ACA-funded tobacco communication campaign, OSH’s ongoing programmatic initiatives, and the Surgeon General’s reports. 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. **Attachment 3** provides an overview of projected program needs during this time period and estimated burden to respondents. At this time, CDC is submitting a revision request to adjust the estimated annualized number of responses and burden hours. The adjustments will be in effect through the remainder of the current OMB approval period (exp. 1/31/2015). Findings from formative work submitted under this revised package will be shared with FDA and other federal agencies as needed.

**Privacy Impact Assessment**

Overview of the Information Collection System

Data collection methods proposed for this generic clearance include, but are not limited to, telephone, in-person, and online interviews and focus groups, surveys and online surveys, cognitive interviews, participant observations, and intercept interviews. In most instances, data will be collected by outside organizations under contract with CDC.

Types of Information to be Collected

Information collection will include needs assessments; demographics, awareness, knowledge, attitudes, beliefs, and behaviors of target respondents; measures of message effectiveness; and audience reactions to test messages.

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.

Respondents participating in each information collection will be informed of the purpose of the information collection and project-specific security measures. Respondents will be assured that their responses will not be shared with anyone outside the project team and that their names will not be reported with responses provided.

Contractors will maintain 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. While this data may or may not be encrypted, 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 evaluation contractors by any survey vendors will be sent via encrypted files.

**Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age**

CDC does not anticipate collecting information from children under 13 years of age using a Website or any other information collection method. Each request submitted under the proposed generic approval will specifically address this issue.

**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 the ongoing ACA-funded tobacco prevention and control campaign. While the list below is meant to be illustrative and not all-encompassing, additional information gathered under the proposed generic clearance ICR will be used, among other purposes, to:

* 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.

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 rough cut testing of television, print, 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.

Privacy Impact Assessment

All respondents will be assured that the information will be used only for the purpose of this information collection and will be kept secure to the extent allowable by law, as will be detailed in a project-specific consent process for each information collection request submitted under the MTTCA generic clearance. Respondents will be assured that their responses will not be shared with anyone outside the information collection team and that their names will not be reported with responses provided.

Each proposed information collection will be submitted to OMB for approval.  The purpose, methods, privacy protections, privacy act determination, incentives, and analysis plan will be described for each project-specific request.

**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. 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 ease 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]](#footnote-9)

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 serve as information channels and help prevent redundancy. Ongoing communication between CDC’s Office of Smoking and Health, and FDA’s Center for Tobacco Products will ensure that information collections are coordinated and not duplicative. 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 coordinated on all 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. 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 weekly calls with their Health Communication and Education staff. OSH/HCB has also shared this revision package with FDA staff as well as findings from their 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. CDC’s submission of this revision request has been coordinated through HHS ASPE.

**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]](#footnote-10) Untested messages can also have unintended consequences, such as jeopardizing the credibility of Federal health officials.[[10]](#footnote-11)

**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 29, 2013, Vol. [78], No. [168], pp. [53461-53463] (**Attachment 2a**). One public comment was received and acknowledged (**Attachment 2b**).

**A.8.b. Consultation**

The following individuals outside of the agency have been consulted on the audience questionnaire development. For additional consultants please see **Attachment 5**.

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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**

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) will 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. Typically, surveys conducted through online panels use already-established records systems. Such records systems typically separate personally identifying data from survey data and only use personally identifying information for purposes of panel maintenance and disbursement of compensation/incentives.

Work may be conducted through contractors carrying out campaign activities but, in all cases, HCB will review the proposed data management procedures and require appropriate safeguards for respondents.

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.

***Example Safeguards for In-Person and Telephone Interviews, Focus Groups, and Intercept Interviews***

Respondents will be advised of the nature of the activity, the length of time it will require, and that participation is purely voluntary. Respondents will be assured that no penalties will be incurred if they wish not to respond to the information collection as a whole or to any specific questions. These procedures conform to ethical practices for collecting data from human participants.

If 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.

***Example Safeguards for Online and Other Technologically-Assisted Data Collections***

Online data collections will conform totally 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 meaning of confidentiality, particularly as it relates to handling 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.

**A.11. Justification for Sensitive Questions**

The majority of questions asked will not be of a sensitive nature. There will be no requests for a respondent’s Social Security Number (SSN).

It will, at times, 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).

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 and the total estimated annualized burden for focus groups is 360 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 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.

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.) | 67 | 1 | 1 | 67 |
| Focus Groups (In Person) | 160 | 1 | 1.5 | 240 |
| Focus Groups (Online) | 120 | 1 | 1 | 120 |
| Short Surveys  (Online, Bulletin Board, etc.) | 6,500 | 1 | 10/60 | 1,083 |
| Medium Surveys  (Online) | 8,500 | 1 | 25/60 | 3,542 |
| In-depth Surveys (Online) | 1,500 | 1 | 1 | 1,500 |
|  | Total | 36,847 |  |  | 7,219 |

**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 | $22.89 | $15,268 |
| General Public and Special Populations | In-depth Interviews (In Person, telephone, etc.) | 67 | $22.89 | $1,534 |
| Focus Groups (In Person) | 240 | $22.89 | $5,494 |
| Focus Groups (Online) | 120 | $22.89 | $2,747 |
| Short Surveys  (Online, Bulletin Board, etc.) | 1,083 | $22.89 | $24,790 |
| Medium Surveys  (Online) | 3,541 | $22.89 | $81,053 |
| In-depth Surveys (Online) | 1,500 | $22.89 | $34,335 |
|  | **Total** | | | **$165,221** |

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 March 2011 the national average hourly wage is $22.89. 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 $165,221 per year.

**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 generic MTTCA clearance was initially approved with the following estimates: 5,775 annualized burden hours and 14,974 annualized responses. The initial estimates were based on the number of respondents who were likely to participate in information collection activities such as focus groups, interviews, and surveys. The initial estimates did not account for specific screening activities that are necessary to identify respondents from key target audiences. In addition, GenICs were configured in a way that overestimated the number of discrete respondents (for example, an individual who participated in screening, followed by participation in an interview, was counted as two responses instead of one respondent). As a result, the initial MTTCA clearance underestimated the total number of responses associated with information collection. The planned revision will adjust for screening and recruitment by allocating 20,000 additional responses to the pool of annualized responses, and 667 additional burden hours for screening. To accommodate both planned activities and potential new initiatives or collaborations, we are also requesting modest increases in the number of responses associated with short, medium and in-depth surveys. The increases in respondents and burden hours are summarized below.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Original Approval | | Revision | | | |
| Data Collection Method | No. Respondents | No. Burden Hours | No. Respondents | No. Burden Hours | Increase in Respondents | Increase in Burden Hours |
| Screening and Recruitment | 0 | 0 | 20,000 | 667 | 20,000 | 667 |
| In-depth Interviews | 67 | 67 | 67 | 67 | 0 | 0 |
| Focus Groups (In Person) | 160 | 240 | 160 | 240 | 0 | 0 |
| Focus Groups (Online) | 120 | 120 | 120 | 120 | 0 | 0 |
| Short Surveys | 6,001 | 1,000 | 6,500 | 1,083 | 499 | 83 |
| Medium Surveys | 7,334 | 3,056 | 8,500 | 3,542 | 1,166 | 486 |
| In-depth Surveys | 1,292 | 1,292 | 1,500 | 1,500 | 208 | 208 |
| Total | 14,974 | 5,775 | 36,847 | 7,219 | 21,873 | 1,444 |

The revised number of annualized responses will increase to 36,847 and the revised total annualized burden hours will increase to 7,219.

**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 and 2 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.

Additional testing related to the ACA-funded campaign will be fielded throughout the remainder of the OMB approval period. Information collections necessary for development and improvement of ACA campaign messages, and adapting materials currently available through the MCRC for specific audiences, will be conducted iteratively throughout this period.

Results that may be of interest to health communicators may be disseminated through presentations at professional meetings and publications.

**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.

1. (National Cancer Institute, 2008, *Making Health Communication Programs Work,* <http://www.cancer.gov/cancertopics/cancerlibrary/pinkbook>). [↑](#footnote-ref-2)
2. Roper, W.L. 1993. Health Communication Takes on New Dimensions at CDC. *Public Health Reports*, 108(2), 179-183. [↑](#footnote-ref-3)
3. Fishbein, M. & Yzer. 2003. Using Theory to Design Effective Health Behavior Interventions. *Communication Theory*, 13(2), 164-183 [↑](#footnote-ref-4)
4. Thackeray & Neiger. 2000. Establishing a Relationship Between Behavior Change Theory and Social Marketing. *Journal of Health Education*, 31(6), 331-335. [↑](#footnote-ref-5)
5. Noar, S. 2006. A 10-Year Retrospective of Research in Health Mass Media Campaigns. *Journal of Health Communication*, 11, 21-42. [↑](#footnote-ref-6)
6. Andreasen, A. 1995. *Marketing Social Change*. San Francisco, Jossey-Bass. [↑](#footnote-ref-7)
7. 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. [↑](#footnote-ref-8)
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. [↑](#footnote-ref-9)
9. Wallendorf, M. (2001) Literally literacy. *The Journal of Consumer Research, 27(4)*: 505-511. [↑](#footnote-ref-10)
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. [↑](#footnote-ref-11)