**Supporting Statement A For:**

**Health Information National Trends Survey 4 (HINTS4)**

**(NCI)**

**OMB No: 0925-0538, Expiry Date 10/31/2014**

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This submission is a Reinstatement with Changes.

Yellow Highlights indicate changes from the 2011 submission.

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A. JUSTIFICATION

This is a request for OMB to reinstate with change an additional round of data collection for the Health Information National Trends Survey (HINTS) for 1 year.

# A.1 Circumstances Making the Collection of Information Necessary

The National Institutes of Health (NIH), in pursuit of its stated mission to “seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability,” provides leadership and guidance to initiatives and programs of research designed to improve the health of the nation through the collection, dissemination, and application of information in health and medicine. As the principal agency for cancer research, the National Cancer Institute (NCI) is responsible for conducting, supporting and disseminating the results of cancer-related research across the cancer care continuum. Thus, NCI maintains the vital mission of facilitating and informing the process by which cancer information is communicated to the public.

The task of collecting data relevant to cancer communication falls to the Health Communication and Informatics Research Branch (HCIRB), Division of Cancer Control and Population Science at NCI. The HCIRB seeks to advance communication and information science across the cancer continuum—prevention, detection, treatment, control, survivorship, and end of life. The primary goals for the HCIRB are (1) to encourage programmatic and interdisciplinary approaches to cancer communication research and (2) to accelerate development of innovative health communication models, theories, and research strategies in cancer prevention, control, and care.

HINTS is specifically designed provide a means to address health communication issues that have not been adequately studied through other data collection efforts. The NCI developed HINTS to monitor population trends in cancer communication practices, information preferences, risk behaviors, attitudes, and cancer knowledge. This survey, increasingly referenced as a leading source of data on cancer communication issues, provides unique population data on changing patterns, needs, and information opportunities in health; identifies changing health communications trends and practices; assesses cancer information access and usage; provides information about how cancer risks are perceived; and offers a test-bed to researchers to investigate new theories in health communication. NCI recognizes that the recent advances in communication technologies have created an “extraordinary opportunity” to invest in cancer communication research (see The Nation’s Investment in Cancer Research: A Plan and Budget Proposal for Fiscal Year 2006 at <http://plan2006.cancer.gov/>). As a vehicle to monitor trends in information preferences, cancer knowledge, and behaviors related to cancer prevention, HINTS provides a powerful way to inform decisions about topics and methods of information dissemination by NCI, as well as to monitor the impact of information disseminated (e.g., how changes in recommendations affect screening behavior).

The Public Health Services Act, Sections 411 (42 USC *§* 285a) and 412 (42 USC *§* 285a-1.1 and 285a-1.3), outline the research and information dissemination mission of the NCI which authorizes the collection of this information. HINTS is specifically designed to support this mission by providing a means to address health communication issues that have not been adequately studied through other data collection efforts. NCI has worked closely with the Federal Drug Administration (FDA) to develop this round of HINTS. Legal justification for a national survey of adult tobacco use can be found in the Family Smoking Prevention and Tobacco Control (TCA)[[1]](#footnote-1) Section 904(d) which authorizes the FDA to conduct research to support tobacco regulation.

***History of HINTS***

NCI funded the first HINTS in June 2001 (OMB #0925-0507, Exp. Date: 8/31/03) and HINTS 1 was administered in 2002 and 2003. In an effort to address diminishing response rates, HINTS 2 (OMB #0925-0538, Exp. 11/30/2007) was conducted in 2005. HINTS 3 (OMB #0925-0538, Exp. 11/30/2008) conducted in 2008 and included the full questionnaire administered via computer-assisted telephone interview (CATI). HINTS 4 (OMB #0925-0538, Exp. 10/31/2014)

addressed emerging issues in the field of health communication while still maintaining the ongoing measurement of trends. HINTS 4 included 4 data collection cycles (fielding 2011-2014). The instrument for each data collection cycle included a core module of trended items in addition to special topic modules implemented in only some of the cycles, increasing capacity of the HINTS instruments to include additional topics and measures. For a full history of HINTS 1 through 4 see **Appendix A.** Though the proposed round of HINTS uses the same methodology and the same cover letters (**Appendices J and K**) as other data collections in HINTS 4, the instrument is substantially different.

***Priorities for HINTS***

The HINTS program aims to further the fields of cancer communication and health behavior, and to ensure that findings from this research are employed to guide the development of policies, programs, and practices at national, state, and local levels. As such, NCI has developed products including HINTS Briefs for audiences who are the “results users” of research findings. NCI has made considerable efforts to ensure ready access to HINTS program information, data, and results for different types of users. To encourage access to and use of the HINTS data, NCI has made the survey questions, data, and results available via the HINTS website (<http://hints.cancer.gov>). The website provides background information about the goals of the survey and connects those who use the site to survey questions, documentation (e.g., sampling plan, codebooks), reports, and HINTS data in multiple formats.

Because of its primary focus on health communication access, usage, and cognitions, the proposed round of HINTS data collection is uniquely positioned to examine the communication-related constructs of HINTS in partnership with relevant FDA health communication endeavors. By keeping to the protocol developed for HINTS 4 (postal administration using print instruments), this set of HINTS items can maximize opportunities to display images such as product labels and advertising claims, and measure knowledge, attitudes, beliefs, and intentions resultant of exposure to those images. Three FDA entities have partnered with NCI to develop unique content for this round of HINTS: FDA’s Office of the Commissioner, the Center for Food Safety and Applied Nutrition, and the Center for Tobacco Products. Priority constructs for measurement in this survey include medical devices; communications related to product recalls; nutritional supplements and anti-carcinogenic labels; knowledge of cancer causes and cancer risk perceptions; and topics to inform FDA’s regulatory authority over tobacco, such as risk perceptions about new tobacco products, product pack color gradations, perceptions of product harm, and tobacco product claims and labels. Importantly, this instrument will include the “HINTS Communication Core,” which is a battery of items related to media use and attention and Internet access and usage. The communication core is unique to the HINTS program. As such, both NCI and the three FDA partners will be able to assess how the medical device, supplement labeling, and tobacco items are associated with media and Internet use and the broad communication environment related to cancer prevention.

# A.2 Purpose and Use of the Information

HINTS provides NCI with a comprehensive assessment of the American public’s current access to, and use of, information about cancer across the cancer care continuum from cancer prevention, early detection, diagnosis, treatment, and survivorship. The content of HINTS focuses on understanding the degree to which members of the general population understand vital cancer prevention messages. More importantly, this NCI survey couples knowledge-related questions with inquiries into the communication channels through which understanding is being obtained, and assessment of cancer-related behavior. The planned HINTS survey continues the overall cancer communication goals of HINTS, maintains the “communication core” that is unique to HINTS, and extends its priorities to include assessments of knowledge of medical devices, communications related to product recalls, nutritional supplement labeling, and topics to inform FDA’s regulatory authority over tobacco, such as risk perceptions about new tobacco products, product pack color gradations, perceptions of product harm, and tobacco product claims and labels. Survey instruments in English and Spanish are attached as **Appendices B1 and B2**.

## Research Questions

The analyses enabled by the survey will allow NCI, FDA, and the cancer communication community to refine its communication priorities, identify deficits in cancer-related population knowledge, and develop evidence-based strategies for selecting the most effective channels to reach identified demographic population groups, including typically underserved populations such as minorities, persons living in poverty, and those who are disproportionally affected by tobacco-related health outcomes. HINTS specifically will provide the only source of data available to answer the following research questions and monitor trends in the answers over time:

* **Research Question 1:** How do people want to obtain information about health-related issues, and specifically those related to FDA product recalls and medical devices?
* **Research Question 2:** Through what media channels do people currently hear about product recalls, and how soon do they act on the information?
* **Research Question 3:** How do people interpret nutritional supplement labels that purport to be “anti-carcinogenic?”
* **Research Question 4:** Considering the full range of communication channels, what are the major sources of tobacco information for the American public?
* **Research Question 5:** To what extent is access or lack of access to different sources of health information associated with tobacco and food safety knowledge or behaviors?
* **Research Question 6:** How trustworthy are the sources of health information (including the FDA and other government agencies) perceived to be, and how satisfied are respondents with information access and content?
* **Research Question 7:** How are tobacco use behaviors related to sources of information and their use?
* **Research Question 8:** How is people’s attention to and trust in health information sources associated with their tobacco use behaviors, perceptions of the harms of tobacco products, and beliefs about tobacco product constituents?
* **Research Question 9:** What do people believe about potential modified risk tobacco product claims, and how are those beliefs distributed by use of communication sources and tobacco use behaviors?
* **Research Question 10:** What is the level and frequency of exposure to specific tobacco messages, and through what channels? How does exposure vary by tobacco use status?
* **Research Question 11:** What are the reasons people would or would not be interested in viewing a publicly displayed list of the harmful and potentially harmful constituents in tobacco products (as is mandated by the Tobacco Control Act Sec. 904(d)), and where would they expect to find such a list?

## Audiences for Data and Results

The authors of the Healthy People 2020 initiative argue that effective use of “communication and technology by health care and public health professionals can bring about an age of patient- and public-centered health information and services”. Developing effective health communication messages is relevant to myriad stakeholders because health communication can contribute to all aspects of disease prevention and health promotion. Some of the targeted beneficiaries of HINTS data are listed below.

* **U.S. Food and Drug Administration (FDA)**: Colleagues at the FDA have developed and contributed a series of items to this survey to assess communications and beliefs about tobacco, and beliefs and actions around medical products and dietary supplements. FDA’s Center for Food Safety and Applied Nutrition will use the data to examine how consumers understand the nature of cancer and certain cancer-related labeling statements that may appear on dietary supplement products. The FDA Office of the Commissioner will provide results from the data to appropriate Centers to learn more regarding consumers’ attitudes about how they wish to deal with recalls and product warnings. For the tobacco-relevant items, FDA has specific plans for use of its data to meet its mandate by the Family Smoking Prevention and Tobacco Control Act (FSPTCA) for meaningful and effective tobacco product regulations. FSPTCA authorizes FDA to regulate tobacco-product advertising, labeling, and marketing and gives authority to conduct public education campaigns.
* **FDA Stakeholders**: As a regulatory agency, FDA stakeholders will benefit from the data collected by HINTS. These stakeholders include academics conducting research on relevant issues on health communication related to tobacco, foods and medical products, as well as regulated industries.
* **Centers for Disease Control and Prevention – Office on Smoking and Health**: Colleagues at CDC-OSH will likely also have uses for this HINTS data to inform their tobacco prevention and control efforts, including media campaigns and surveillance of tobacco-related beliefs. CDC colleagues have reviewed the draft instrument and provided feedback to NCI.
* **Office of Disease Prevention and Health Promotion (ODPHP)**: In developing their list of objectives for Health Communication and Health Information Technology, the Office of Disease Prevention and Health Promotion in the Department of Health and Human Services contacted NCI staff to plan objectives around existing and planned HINTS communication core measures. The Office of Disease Prevention and Health Promotion at the Department of Health and Human Services (HHS) named HINTS as a data source to assess progress on several of their Health Communication and Health Information Technology Objectives for Healthy People 2020.
* **United States Congress**: FDA is required to “conduct periodic consumer research” on a number of topics, including on lists of harmful and potentially harmful constituents (Sec. 904(e) of the Tobacco Control Act), results from HINTS will be included in those reports to Congress.
* **Public Health Professionals**: They will be provided with data on which to base their communication decisions.
* **Behavioral and Communication Researchers**: They benefit from new data to inform the next generation of behaviorally oriented communication theories and to test specific hypotheses within the context to the topics addressed in this survey.
* **Health Care Professionals:** They benefit directly from information about how the general public is acquiring its health-related information to accommodate their patients’ health information needs.

## Methods of Dissemination

As with all previous rounds of HINTS, data from this HINTS data collection will be made available for public use following the removal of all identifying information, such as names, addresses or telephone numbers. Data files will be prepared in accordance with standards for protecting the privacy of the participants. HINTS 4 data will then be made available through various mechanisms as described below.

* **Reports.** NCI prepares descriptive reports summarizing the data in terms of cancer knowledge, preventive behavior, and communication preferences. These reports are available in hard copy and over the Internet on the HINTS web site (<http://hints.cancer.gov>/).
* **Raw Data.** As with all HINTS data, the data files and documentation from this round of HINTS will be made available via the HINTS web site. This data is meant for researchers who are able to conduct fairly complex analyses.
* **Data Summaries.** In addition to the raw data files, NCI will add the new HINTS data to the electronic codebook (found at [http://hints.cancer.gov](http://cancercontrol.cancer.gov/hints)/) that allows interaction with the data (e.g., graphical representations of frequency data can be displayed easily) and can be downloaded for reports and manuscripts. This resource is targeted to policy makers, public health professionals or others who do not want or are not able to conduct their own analyses.
* **Presentations and Publications.** NCI and FDA staff, as well as researchers in food safety, risk communication, tobacco control, and cancer and health communication who access the raw data will prepare presentations to be made at national conferences such as the American Public Health Association, the Society of Behavioral Medicine, Society for Research on Nicotine and Tobacco, the International Communication Association, and the American Association of Public Opinion Researchers in addition to the HINTS Data Users Conference, which is held every 2-3 years. In addition, research on cancer and health communication is summarized and submitted to peer-reviewed research journals such as the *American Journal of Public Health*, *Journal of the American Medical Association*, *Journal of Preventive Medicine*, *Journal of Preventive Oncology*, *Health Psychology*, and *Journal of Health Communication*. For a list of publications of HINTS data, see **Appendix C.**

# A.3 Use of Information Technology and Burden Reduction

Data collection will be conducted using a paper instrument. Respondents will not be offered an option for electronic response. Although consideration was given to providing respondents a choice between a paper and a web-based instrument, this dual-mode design was ultimately rejected because a number of studies have shown that giving respondents a choice between modes depresses response rates (Griffin, 2001; Dillman, et.al., 2009; Gentry and Good, 2008; Messer, 2009).

An information technology system will be used to track respondents and store and maintain the data. A Privacy Impact Assessment (PIA) for HINTS was initiated through NCI’s Privacy Act Coordinator. See **Appendix D** for a copy of the PIA submitted.

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

***Collaboration and Coordination with Federal Partners.***

With respect to development this HINTS instrument, our team benefitted greatly from participating in the June 6, 2013 meeting with OMB staff, and gained a better understanding of how this survey is positioned within the larger strategic plan for federal tobacco-related surveys. Although this version of HINTS is not a tobacco surveillance survey *per se* (only 45% of the instrument covers tobacco topics), but rather a health communication survey with items unique to HINTS, we do appreciate the need to harmonize and reduce duplication in the tobacco-related items funded by FDA’s Center for Tobacco Products, as appropriate. In advance of submitting this request, the HINTS team coordinated with other federal partners to inform the development of this survey.

First, in advance of pursuing approval to perform cognitive testing this version of the HINTS survey, the team explored the Centers for Disease Control and Prevention’s (CDC) Q-Bank database (<http://wwwn.cdc.gov/qbank/Home.aspx>) of cognitive testing reports to assess the extent to which we could learn from the tobacco and health communication items that previously had been cognitively tested for other national surveys. We also reviewed and documented areas of duplication with other federal surveys and adjusted our cognitive testing and instrument development plans accordingly.

During the development of this HINTS survey item pool and in preparation for cognitive testing, the research team canvassed major data collection efforts to assess the degree to which other surveys collect and report data relevant to the tobacco items planned for this HINTS survey. In addition, the research team consulted with other agencies within the Department of Health and Human Services (HHS) to identify potential duplication of effort and areas for burden reduction between surveys. Those efforts were described in the OMB package approved for cognitive testing (OMB No. 0925-0589-06, Exp. 4/30/2014).

Since that time, this HINTS survey instrument has been revised to reflect the results of cognitive testing and an additional round of review by federal partners in August 2014, in order to further reduce duplication with other federal data collection efforts.

***Canvassing other Federal Tobacco Surveys***

**Appendix E** provides an updated spreadsheet that details the major sources reviewed during the canvassing of other federal tobacco surveys, and the results of the review. Efforts have been made to include similar wording and response options when similar items were found in other surveys. Including those items should provide comparability with other data sources and provide value to the Government by allowing it to make inferences across data collection efforts. Results of the source review indicated that no existing survey adequately covered the topic areas central to this HINTS instrument. Items in other public data collections related to tobacco (e.g. National Youth Tobacco Survey, National Adult Tobacco Survey, Population Assessment of Tobacco and Health Study[[2]](#footnote-2)), obtain data about respondents’ tobacco use behaviors and contain a limited number of knowledge and attitude questions, and even fewer items, if any, on the communication concepts assessed in HINTS, and do not connect specific knowledge/attitudes/perceptions about tobacco and other non-tobacco topics to health communication variables. The key differences between the HINTS instrument and tobacco items on other surveys are outlined in more detail below.

* HINTS is only administered to adults whereas a number of other surveys (NYTS, PATH, MTF, YRBS, and NSDUH[[3]](#footnote-3)) include youth samples or are only administered to youth samples.
* The tobacco use behavior questions on HINTS do not serve the same purpose as on other surveys. Those surveys use the information to establish prevalence estimates, track patterns of use, and monitor the impact of policies on use. In HINTS, these items, of which we use a restricted set of commonly-accepted and used measures of tobacco use, serve to segment the respondents and look at associations between tobacco use and the other sections of the instrument that do not appear on other surveys, mainly media use and exposure and communication items. For example, an analysis from HINTS might explore the following research question: “Do current cigarette smokers differ in their trust of tobacco health information from various sources compared to non-smokers and/or current users of other tobacco products? How is that association influenced by health information seeking behavior about tobacco?” Although some of these items are duplicated on other national surveys, their inclusion with the other communication-specific constructs unique to HINTS is necessary because those analyses must use constructs from the same dataset.
* Although other national surveys do include a few communication questions, they mainly focus on the amount of use of various forms of media (e.g. hours spent watching TV), but do not focus on trust in health information from those sources, or other communication-related questions that are unique to HINTS data.
* Similarly, for exposure questions (Tobacco Message Exposure Source/ Frequency/ Reaction), other surveys that include similar items tend to focus on direct promotion by tobacco companies (e.g., getting coupons in the mail), but do not go into the same level of detail that HINTS will on the type of message, the channel through which it was observed, and the frequency of noticing the message. This level of detail is critical to inform the Food and Drug Administration’s Center for Tobacco Products’ (CTP) communications efforts as CTP is actively planning a number of media campaigns and other communication efforts.

Items from existing private, nonpublic use surveys of communication (e.g., UCLA, Pew Charitable Trust, Georgia Tech, and Harris Poll) also were reviewed. While they cover topics related to general Internet usage, they do not relate online communication endeavors directly to cancer communication or the constructs of interest for the HINTS survey.

***November/December 2013 Review by Federal Partners***

Feedback gathered by consulting with and circulating the cognitive testing version of this HINTS instrument in late 2013 proved invaluable and improved the instrument and data collection plans significantly. Upon reviewing the HINTS cognitive testing instrument, CDC provided item-specific comments and edits (mostly related to period of recall for tobacco-specific items) which will help to harmonize data collection efforts and reduce duplication and burden. They also provided insight about the reading level of the instrument, which was taken under consideration in the development of the final instrument.

A review of the draft cognitive testing instrument by NIDA colleagues who are involved in the PATH study revealed no significant overlap in HINTS and PATH. Item-specific feedback from NIDA included wording changes that will make the tobacco questions more comparable to PATH, where applicable. For example, product brand names were added to existing lists. Federal colleagues involved in the 2013 review of the HINTS cognitive testing instrument are included in the list found in **Appendix F.**

***August 2014 Review by Federal Partners***

Upon incorporating feedback from CDC and NIDA, and implementing the needed changes resultant of cognitive testing (OMB No. 0925-0589-06, Exp. 4/30/2014). NCI worked with ASPE to coordinate a second review of the HINTS instrument in July and August 2014. ASPE provided names of additional federal staff who work on tobacco-related data collection efforts. Those staff were asked to review both the near-final survey instrument and the spreadsheet (**Appendix E**) that delineates potential areas of overlap and harmonization with other federal surveys. This second review of the instrument provided valuable feedback that has helped us to revise the spreadsheet and the instrument, where appropriate, to reflect the state-of-the-science in tobacco control and health communication, and to better position the unique health communication focus of HINTS within other federal tobacco surveys. Feedback and resultant changes are summarized below.

Colleagues at NIDA who work on the PATH study commented on several aspects of the instrument, as well as worked closely with NCI to decide on appropriate images to use to represent hookah, snus, and e-cigarettes. Their helpful feedback on how best to word items that require retrospective recall by respondents resulted in changes throughout the instrument, to better reflect desired recall from the “past 12 months.” Their comments on items D15 and D16, which assess beliefs about FDA regulatory authority over tobacco, helped us to think about how best to assess beliefs in this area, and how to compare suggested wording with wording from questions that are being trended across HINTS.

Colleagues from CDC/OSH provided an in-depth review of the instrument, which resulted in several edits and changes, as well as several ideas for future collaboration on studies in the area of trust in government agencies as sources of tobacco information. Some of the OSH comments about adding assessments about dissolvable tobacco products could not be incorporated because they are out of the scope of the current survey. Many other comments, however, resulted in significant changes to the instrument. For example, OSH’s thoughtful response about how best to define ENDS resulted in us adding parenthetical examples of additional ENDS to every e-cigarette question throughout the instrument (“also known as vape-pens, hookah-pens, e-hookahs, or e-vaporizers.”) We have also repeated the ENDS image in a second section of the survey, in order to assist respondents with their responses. OSH’s comments about the assessment of smoking status (C1) resulted in removing a skip pattern to allow a more robust assessment. They also helped us to refine our quitting and harm perception questions, and to think about our questions related to modified risk claims and beliefs about FDA regulatory authority.

The HINTS instrument benefitted tremendously from the review, and the resultant revised instrument is stronger for the effort. The federal colleagues who provided the July/August 2014 review of the instrument are included in **Appendix F.**

# A.5 Impact on Small Business and Other Small Entities

No small businesses will be involved in this study.

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# A.6 Consequences of Collecting the Information Less Frequently

As its name implies, the Health Information National Trends Survey is designed to identify trends in national health information over time. This round of HINTS will be the fifth iteration of this cross-sectional survey of the civilian, noninstitutionalized, adult U.S. population. Less frequent data collection would result in incomplete tracking of these trends. However, this submission is requesting clearance for a one-time data collection (i.e., respondents are not expected to answer this survey more than once and will not be recontacted). Separate requests will be submitted for future rounds of HINTS data collection.

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

There are no special circumstances related to the national survey that would cause the information collection to be conducted in a manner inconsistent with 5 CFR 1320.5.

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

The 60-Day Federal Register notice soliciting comments on this study prior to initial submission to OMB was published on December 4, 2014 (Vol. 79, No. 233, pages 72003 – 4). A total of five public comments were received. The first two, received December 3 and December 4, 2014, requested study materials. Statement A, Statement B and the survey instrument were sent via email to both requestors on December 8, 2014. Two comments were received from the same person, one on December 6 and one on December 7, 2014. Both comments stated that the study was a waste of government funds. A response was sent on December 12, 2014 thanking the respondent for her feedback. A final comment was received on February 2, 2015 stating that the proposed study is duplicative of existing government surveys on tobacco. A response was sent on February 2 thanking the respondent for his feedback.

The HINTS program has always relied on the participation of a wide variety of researchers and practitioners to develop the survey instruments. For this HINTS instrument, development of the items to be included involved subject-matter experts at the Food and Drug Administration’s Center for Tobacco Products (CTP) including many individuals within the Office of Science directly working on other national data collections such as NYTS, NATS, TUS-CPS and PATH as well as CTP’s public education campaigns in CTP’s Office of Health Communication and Education. Additionally for the tobacco-related items, experts from CDC’s Office on Smoking and Health provided feedback, as well as scientists from NIDA, and numerous academic researchers with specific expertise in item content provided sample items. Experts in FDA’s Center for Food Safety and Applied Nutrition (CFSAN), and Office of the Commissioner (OC) provided content relevant to medical devices, product recalls, nutrition supplement labeling, and cancer risk perceptions. See **Appendix F** for a list of people consulted.

# A.9 Explanation of Any Payment or Gift to Respondents

We are proposing to continue including a $2 incentive in the first mail out of the questionnaire. Incentives are known to significantly increase response rates to mail surveys (Church, 1993; Dillman, et al., 2009). Church (1993) reports an effect size of almost 20 percentage points, although it varies by incentive amount. There is also evidence that an incentive in this context increases the response among young people. This group is particularly important for HINTS because they tend not to respond to health-oriented surveys, like HINTS (Cantor, 2010). A previous round of HINTS did an experiment on the pilot study examining the effects of this type of incentive on response rates and found that it increased rates by approximately 10 percentage points (Cantor et al., 2007). On the basis of this experiment, HINTS routinely uses a $2 incentive (Westat, 2009).

# A.10 Assurance of Confidentiality Provided to Respondents

The NIH Privacy Act Officer has reviewed this survey and methodology and has determined that the Privacy Act does apply to this collection of information. The NIH Privacy Act System of Record Number is 09-25-0156, “Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD,” and was published on 9/26/2002 (67 FR 60743). See **Appendix G** for the Privacy Act Memo. Volunteers who participate in this study will be subject to assurances and safeguards as provided by the Privacy Act of 1974 (5 USC 552a), which requires the safeguarding of individuals against invasion of privacy. The Privacy Act also provides for the privacy of records maintained by a Federal agency according to either the individual’s name or some other identifier. All members of the HCIRB and staff working with HINTS data will adhere to the provisions stipulated within that announcement.

Westat, the study contractor, has its own policy and procedures regarding confidentiality and a pledge that all employees must sign (see **Appendix H**). Westat provides all safeguards mandated by the Privacy Act to protect the privacy of data gathered for this study. Westat data security procedures comply fully with procedural safeguards for computerized records as outlined in the U.S. Department of Health and Human Service’s *General Administrative Manual* under “Safeguarding Records Contained in Systems of Record” and specified by the National Institute of Standards and Technology Federal Information Processing Standards (FIPS).

HINTS received its original exemption from the NCI Office of Human Subjects Research on June 23, 2011. An amendment was submitted for OHSR #5810 on May 28, 2014 to allow for this round of HINTS, following the same procedures and considerations for the protection of human subjects. On June 5, 2014, NCI’s OHSRP determined that the current data collection effort also is excluded from IRB review. Documentation is provided in **Appendix I.** In addition, Westat has its own internal IRB under provisions specified by its multiple project assurance plan. Westat’s IRB reviewed the proposed HINTS data collection materials on July 31, 2014. Westat’s IRB chairperson, Kerry Levin, indicated that this project has been provided an expedited approval. IRB documentation is also provided in **Appendix I.**

# A.11 Justification for Sensitive Questions

Respondents will be asked slightly sensitive questions that are about their health, health-related risk behaviors, health communication practices, and tobacco use. All of these potentially sensitive topics are essential to the objectives of HINTS.

Personally identifiable information (PII) will be collected as part of this data collection effort. All selected households will be assigned a study ID. The study management system (SMS) will contain both the selected household’s address and the study ID, but no names. Data is maintained in a separate database from the SMS or address information. Only a limited number of Westat project staff will have access to the SMS. The SMS will be maintained on a restricted-access drive within the Westat firewall. Completed paper questionnaires will be kept in a locked location. Once scanned, data will be maintained on a secured database within the Westat firewall and will be accessible by only a limited number of Westat project staff. Data will be identified only through the study ID. No names or identifiers will be used in reports or delivered to the NCI as part of the final dataset.

Study procedures will be designed to make respondents feel as comfortable as possible in answering these questions. These procedures will involve assuring respondents of the privacy of their responses and of the voluntary nature of their participation in the survey or any of its components, including the option to skip specific questions that they may prefer not to answer. Furthermore, participants’ names will not appear on any study documents. A crosswalk between study ID and participant address will be kept in a secured electronic file and will be accessible only to those working on the study. The linkage between study ID and personal identifiers will be destroyed upon completion of the study.

# A.12 Estimates of Hour Burden Including Annualized Hourly Costs

The annual hour burden and the annualized cost for this HINTS survey are shown in Tables A12-1 and A12-2, respectively below. The burden estimate is based on self-reported data from HINTS 4, Cycles 1-3 in which respondents reported that it took them an average of 30 minutes to complete the mail survey. We anticipate this HINTS instrument to be approximately the same length. The total estimate of respondent burden is 2,159 hours over for the one year request for approval. The total and annualized cost is calculated with a wage rate of $22.33 per hour to be $48,210. The wage rate was obtained from the May 2013 Bureau of Labor Statistics (<http://www.bls.gov/oes/2013/may/oes_nat.htm#00-0000>) title “all occupations,” occupation code 00-0000.

**Table A12-1. Estimate of respondent hour burden**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of Respondent | Number of Respondents | Number of Responses Per Respondent | Average Burden Per Response(in hours) | Total Annual Burden Hour |
| Individual | 4,318 | 1 | 30/60 | 2,159 |

**Table A12-2. Annualized cost to respondents**

|  |  |  |  |
| --- | --- | --- | --- |
| Type of Respondent | Number of respondents | Hourly Wage Rate | Respondent cost |
| Individual | 4,318 | 22.33 | $48,210 |

# A.13 Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers

There are no costs to respondents beyond those presented in Section A.12. There are no operating, maintenance or capital costs associated with the collection.

# A.14 Annualized Cost to the Federal Government

The contractor costs for this HINTS data collection is $833,370. These costs include study design, cognitive testing, sampling, data collection, data cleaning, data weighting, and final reporting. The annual cost of Federal employees (both at NCI and FDA) for monitoring this HINTS survey is estimated to be $235,834. The total and annualized costs for this one-year request are outlined below.

**Table 14-1 Annualized cost to the government**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **NCI Personnel** | **Grade/Step** | **Annual Salary** | **Percent time** | **Total Cost** |
| Project Officer | Title 42 | $180,000 | 25% | $45,000 |
| Program Coordinator | 14/5 | $120,429 | 50% | $60,215 |
| Data Analyst | 14/6 | $123,970 | 40% | $49,588 |
| NCI/HCIRB Program Director | 14/5 | $120,429 | 20% | $30,107 |
| NCI/TCRB Program Director | 14/2 | $109,804 | 10% | $10,980 |
| FDA/CFSAN Consumer Science Specialist | 13/5 | $101,914 | 10% | 10,191 |
| FDA Social Science Analyst | 14/7 | $127,512 | 15% | 19,127 |
| FDA/CTP Social Scientist, Lead | 14/1 | $106,263 | 10% | $10,626 |
| Total government personnel costs | $235,834 |
| Contractor costs | $833,370 |
| **Total cost to the government**  | **$1,069,204** |

# A.15 Explanation for Program Changes or Adjustments

This submission represents a reinstatement with changes that will provide data for comparison with previous HINTS survey data. This special round of HINTS is a result of a partnership between NCI and FDA and offers the opportunity to assess the public’s knowledge of medical devices, communications related to product recalls, nutritional supplement labeling, risk perceptions about new tobacco products, perceptions of tobacco product harm, and tobacco product claims and labels in conjunction with the “core” HINTS questions about health communications. **Appendix L** shows which questions are new to this special round of HINTS data collection. Statement B outlines the slight changes to the sampling procedures for this round of HINTS (to try to get more smokers as HINTS participants). All other materials are the same as for other rounds of HINTS.

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

Analyses of this round of HINTS data will be guided by the research questions articulated in Section A.2. The data will be treated as one of the HINTS datasets and be publically available. Data analysis and publication of results for HINTS by both NCI and outside researchers has been ongoing and prolific. To date, 3,673 researchers have signed up on the HINTS website to get access to the public-use HINTS data sets. The number of known publications based on HINTS data is approximately 160. However, because these numbers are based solely on what has been reported to NCI, these numbers under-represent the actual number of presentations and publications. The publically available database has most likely resulted in other, unidentified publications and presentations. For a list of known publications to date, please see the previously-cited **Appendix C.**

The anticipated schedule for this data collection is outlined in Table A16-1.

**Table A16-1. HINTS Survey Project Schedule**

| **Activity** | **Time Schedule** |
| --- | --- |
| Field Period | 0-4 months after OMB approval |
| Data cleaning and weighting | 5-7 months after OMB approval |
| Analysis started | 8 months after OMB approval |

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

NCI is not seeking an exception to the display of the OMB expiration date.

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

NCI is not requesting an exception to the certification requirements.

1. The Family Smoking Prevention and Tobacco Control (TCA) and Federal Retirement Reform Act was enacted after being signed by the President on June 22, 2009 (Public Law 111-31). <http://www.gpo.gov/fdsys/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf> [↑](#footnote-ref-1)
2. National Youth Tobacco Survey (NYTS), OMB No. 0920-0621, Expiration Date 1/31/2015. National Adult Tobacco Survey (NATS), OMB No. 0920-0828, Expiration Date 7/31/2015. Population Assessment of Tobacco and Health Study (PATH), OMB No. 0925-0664, Expiration Date: 11/30/2015. [↑](#footnote-ref-2)
3. Monitoring the Future (MTF) Survey. Youth Risk Behavior Survey (YRBS), OMB No. 0920-0493, Expiration Date: 9/30/2015. National Survey on Drug Use and Health (NSDUH), OMB No. 0930-0080, Expiration Date: 9/30/2016. [↑](#footnote-ref-3)