

Supporting Statement A For:

Health Information National Trends Survey V (HINTS V) (NCI)

OMB No: 0925-0538, Expiry Date X/X/XXXX

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Check off which applies:

- New
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## **A. JUSTIFICATION**

This is a request to OMB for a reinstatement with change, three additional years of data collection for the Health Information National Trends Survey (HINTS). As in the past, HINTS V will provide 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 the survey will focus on understanding the degree to which members of the general population understand vital cancer prevention messages. More importantly, this NCI survey will couple knowledge-related questions with inquiries into the communication channels through which understanding is being obtained, and assessment of cancer-related behavior. Working with the Office of the National Coordinator, HINTS V will include an additional focus on the public's use of electronic medical and health records.

### **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.

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. 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. As a vehicle to monitor trends in information preferences, cancer knowledge, and behaviors related to cancer prevention, HINTS V 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).

NCI funded the first HINTS in June 2001 (OMB #0925-0507, Exp. Date: 8/31/03) and HINTS I was administered in 2002 and 2003. In an effort to address diminishing response rates, HINTS II (OMB #0925-0538, Exp. 11/30/2007) was conducted in 2005. HINTS III (OMB #0925-0538, Exp. 11/30/2008) conducted in 2008. HINTS IV (OMB #0925-0538, Exp. 10/31/2014) included 4 data collection cycles (fielded 2011-2014) plus a 5<sup>th</sup> round of data collection conducted in partnership with the FDA (HINTS-FDA). The instrument for each data collection in HINTS IV included a core module of trended items in addition to special topic modules implemented in only some of the cycles, increasing the capacity of the HINTS instruments to include additional topics and measures. For a full history of HINTS I through IV, see **Appendix A**. The proposed round of HINTS uses the same methodology and cover letters (**Appendix B**) as HINTS IV, with

changes to the instrument appropriate for tracking current cancer-related health communication trends.

In the past three years, HINTS has collected several rounds of survey data, which have been and continue to be analyzed for the purpose of informing cancer communication efforts. As with all HINTS data, HINTS IV datasets have been made publically available and can be downloaded by researchers in both the public and private sectors for analysis. Each cycle of data is downloaded separately, with Cycle 4 having been downloaded 966 times so far. Other HINTS IV cycles have had similar download rates. HINTS IV data have been widely published and presented by scientists both within NCI, across the Federal government, and within the larger cancer research community. To date, 66 peer-review journal articles and 8 “briefs” (described in section A.2) have been published using data from HINTS IV. For a list of these HINTS IV publications, see **Appendix C.**

### ***Priorities for HINTS V***

When NCI first launched the HINTS program, the biggest change in the communication environment involved the emerging diffusion of electronic networking technology – i.e., the Internet – on the general public’s ability to find and utilize credible health information. In fact, data from the HINTS program has been used by the Healthy People 2010 and 2020 programs to monitor the public’s access to Internet-enabled information resources for health purposes (see Hesse et al, 2014). Since the inception of the HINTS program, the use of digital technologies to support biomedical and public health objectives has broadened greatly. Implementation incentives from the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 have hastened the adoption of Electronic Health Records (EHRs) and their consumer equivalents in Personal Health Records (PHRs). Adoption of mobile connectivity has risen, with dramatic increases in the use of smartphone and tablet technologies to access

Internet resources. Wireless sensors have also begun to proliferate, with wearable devices becoming popular for consumers who are interested in proactively improving their health and for patients who rely on wireless sensors for care, away from the clinic. Indeed, the topic of mobile health (mHealth) has emerged as a point of intense biomedical research. Moreover, the “Precision Medicine Initiative” from the President’s 2015 State of the Union address, and the “Moon Shot in Cancer” initiatives, will rely heavily on advances in patient-facing electronic communication and information technology to achieve their goals. Understanding how the nation is progressing in its use of “Digital Health” tools, as outlined by the President’s Council of Advisors on Science and Technology, will become an important focus of cross-agency research (PCAST 2010, PCAST 2013).

The HINTS surveillance vehicle is ideally situated to monitor the public’s adoption of, and response to, this new round of digital health innovation in healthcare generally, and cancer specifically. The purpose of HINTS V, then, will be threefold:

- To maintain surveillance on core trends related to health communication and informatics. HINTS will continue to be a primary source of surveillance data for the Healthy People 2020 population goals in the area of “Health Communication and Health Information Technology.”
- To focus new content for trending in areas of recent development in the communication environment. In particular, HINTS V will serve as the primary data collection vehicle for the HHS Office of the National Coordinator for Health IT (ONC) in the area of “connected health.” The connected health concept is especially important to the HHS ONC as it rolls out its blueprint for an interoperable (i.e., connected) health care system in the United States. “Connected Health” is also a priority articulated by the President’s Cancer Panel’s upcoming 2016 report to the President of the United States.
- To serve as a research platform into the behavioral, cognitive, and affective aspects of population-based cancer control activities. The HINTS research platform has already produced more than 266 publications from the scientific community. New questions will emerge as cancer control researchers confront the communication challenges associated with President’s Precision Medicine Initiative and the newly announced “Cancer Moonshot,” both of which will emphasize individualized approaches to prevention, treatment, and survivorship.

As with previous rounds of HINTS data collection, HINTS V will explore sampling and methodological issues that can inform future rounds of HINTS as well as the survey research field in general. For HINTS V, a priority for testing is to test a probability strategy for identifying smokers in the general population. This will be done through a pilot study conducted at the same time as the first cycle of HINTS V data

collection. Because the pilot is testing a sample strategy, it will be conducted with a separate sample of respondents than cycle 1. A reinstatement with changes is being sought because the previous HINTS IV submission had finished information collection and additional questions were being created for the HINTS V information collection and the OMB number expired while these changes were being created.

## **A.2 Purpose and Use of the Information**

HINTS V will provide 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 the survey will focus on understanding the degree to which members of the general population understand vital cancer prevention messages. More importantly, this NCI survey will couple knowledge-related questions with inquiries into the communication channels through which understanding is being obtained, and assessment of cancer-related behavior.

### **Information to be Collected**

As with prior HINTS instruments, the HINTS V instruments will include a wide variety of behavioral, attitudinal and belief questions. The instrument for each of the three cycles of data collection will include three types of questions:

1. Core health communications questions for which HINTS is known and which have appeared on every HINTS instrument since 2001. These items are trended over time and contribute a unique set of data to the field of cancer prevention research and they make up a majority of all HINTS instruments.
2. Items developed in conjunction with the ONC and focused on the public's interactions with a connected healthcare system. One of the noted issues in the adoption of health information technologies is that patients' health information may still not be flowing seamlessly between components of a fragmented healthcare system. Creating a more interoperable (i.e., connected) healthcare system is a strong priority for the HHS and for Congress. These collaboratively developed items will assess the general public's use of connected healthcare technologies, along with their perceptions of reliability in enabling a seamless transfer of health information between respondents' providers.
3. Items selected just prior to the fielding. This section of items (the smallest section) is provided to allow the HINTS instrument to be responsive to unanticipated health issues as they arise. Topics



that are anticipated to be covered in this section include specific assessments related to emerging practices in medicine such as those precipitated by the Precision Medicine Initiative;” messaging related to changes in cancer prevention recommendations (e.g., anticipated changes in screening guidelines); and behavioral changes precipitated by the diffusion of new consumer facing health information technologies (such as the recent popularity of “wearable” sensors for meeting personal health goals). It should be noted that although the items in this category have not yet been selected for the second and third rounds of data collection being requested, NCI plans to submit an amendment to OMB prior to each round of data collection. In this way, OMB will have an opportunity to review all questions prior to fielding. No data collection will take place until OMB approval has been granted for each specific data collection instrument. The instrument for the first cycle of data collection is attached as **Appendix D**.

4. The pilot test, intended to oversample smokers, will use the previously-approved HINTS-FDA survey instrument with only minor edits (see **Appendix E**).

## **Research Questions**

The analyses enabled by the survey will allow NCI 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 and persons living in poverty. 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:** Considering the full range of communication channels, what are the major sources of cancer information for the American public?

**Research Question 2:** Have there been population shifts over time in use of major sources of cancer information for the American public?

**Research Question 3:** To what extent is access or lack of access to different sources of health information associated with cancer knowledge or behaviors?

**Research Question 4:** Have there been population shifts over time in access to different sources of health information and are said shifts related to changes in cancer knowledge or behavior?

**Research Question 5:** What segments of the U.S. population depend on information technology (i.e., the Internet) to meet at least some of their cancer information needs?

**Research Question 6:** Have there been population shifts over time in the extent to which segments of the U.S. population depend on information technology (i.e., the Internet) to meet at least some of their cancer information needs?

**Research Question 7:** How trustworthy are the sources of health information perceived to be, and how satisfied are respondents with information access and content?

**Research Question 8:** Have perceptions of trust in and satisfaction with various sources of health information changed over time?

**Research Question 9:** What is the level of knowledge about cancer incidence, etiology, prevention, detection, and treatability and what are the psychological and structural determinants of this knowledge?

**Research Question 10:** Have levels of knowledge about cancer incidence, etiology, prevention, detection, and treatability changed over time in the population and are such changes associated with psychological and structural determinants of this knowledge?

**Research Question 11:** How are cancer prevention behaviors related to sources of information and their use?

**Research Question 12:** Have there been population shifts in cancer prevention behaviors, and do such shifts correspond to changes in use of information sources?

**Research Question 13:** How do people want to get information about cancer-related issues?

**Research Question 14:** Have there been population shifts over time in preferences in the ways in which people want to get information about cancer?

**Research Question 15:** What is the general population's appraisal of the reliability of the healthcare system to meet their ongoing needs, even when care is delivered across several providers?

**Research Question 16:** Are connected health technologies benefiting all population groups equitably; are there some groups that are experiencing unanticipated effects from a move toward digital health services?

**Research Question 17:** How is the public responding to changes in recommendations for cancer prevention, such as recent changes in guidelines for prostate cancer screening, breast cancer screening, and diet?

**Research Question 18:** What does the public understand with respect to medicine's migration toward a more predictive, preemptive, precise, and participative stance toward care?

**Research Question 19:** Is the public willing to engage more proactively with the research enterprise as policies shift toward reciprocal data sharing, and norms toward "crowdsourcing" favor a sense of data altruism?

**Research Question 20:** How well is the evolving platform of connected health technologies serving patients' needs for autonomy, self-management, and engagement with their own care and the care of family members?

## **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.

**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 measures. The Office of Disease Prevention and Health Promotion at DHHS has named HINTS as a data source to assess progress on several of their Health Communication

and Health Information Technology Objectives for 2020. See **Appendix F** for the list of 2020 objectives and sources.

**Office of the National Coordinator (ONC):** The ONC has collaborated with NCI to designate content for inclusion in HINTS V that would assess the impact of health information technology on population health and healthcare. ONC is interested in using HINTS to track the adoption of communication technology and impact on health and healthcare.

**U.S. Food and Drug Administration (FDA) Center for Tobacco Products:** Colleagues at FDA CTP will benefit from new data that will inform their regulatory authority over tobacco, including items that assess exposure to tobacco information and resultant harm perceptions of tobacco products.

**Patient Advocacy Community:** The patient advocacy community relies on HINTS data for population estimates around patient engagement in health and healthcare, patient provider communication, and supporting patient use of available health communication.

**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.

**“Consumer Informatics” Specialists.** They will be able to make important decisions about channels, types of information to publish within those channels, and how best to reach certain populations.

**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.

**Hospital and Healthcare Plan Providers.** Recent legislation is placing greater responsibility on local hospitals and healthcare plans to be proactive in managing the upstream conditions contributing to the health of their members. The HINTS data provide insight from a population level for local action.

## Methods of Dissemination

As with the first three rounds of HINTS, data from HINTS V 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 V 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 de-identified data files and all the documentation necessary to conduct weighted analyses from HINTS V will be made available via the HINTS web site and on CD-ROM for those who do not have Internet access or who request this mode of distribution. These data are meant for researchers who are able to conduct fairly complex analyses. Additionally, efforts have been made to include common data elements when appropriate so that national surveillance researchers can integrate the HINTS data with other relevant public health surveys to obtain a broader, more comprehensive situational awareness.

**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/>) 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.

**HINTS Briefs.** Since its inception, the HINTS program has developed a communication strategy that includes outreach to public health professionals and the general public through the publication of evidence syntheses in the form of HINTS data briefs. The briefs are short, easy to read, and intended to distill knowledge from emerging publications into actionable recommendations based on trends. The program has produced 30 briefs thus far in both English and Spanish.

**Presentations and Publications.** NCI staff, as well as researchers in cancer and health communication who access the raw data, prepare presentations made at national conferences such as the American Public Health Association, the Society of Behavioral Medicine, the International Communication Association, and the American Association of Public Opinion Researchers in addition to the HINTS Data Users Conference, which is held every other year. 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 current list of publications and presentations of HINTS data, see the HINTS website: <http://hints.cancer.gov/research.aspx>

### **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) has been initiated through NCI's Privacy Act Coordinator. See **Appendix G1** for a draft of the the PIA submitted and approved by NCI.

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

During the development of the HINTS item pool, the research team canvassed major data collection efforts to assess the degree to which other surveys collect and report data relevant to these areas. Results of the source review indicated that no existing survey adequately covered the topic areas central to HINTS. Items from the existing Internet surveys (e.g., UCLA, Pew Charitable Trust, Georgia Tech, and

Harris Poll) cover topics related to general Internet usage, but do not relate on-line communication directly to relevant issues regarding cancer or cancer communication. Similarly, items in the health surveys (e.g., NHIS-Cancer Supplement and Behavioral Risk Factor Surveillance System) obtain data about respondents' behaviors and contain a limited number of knowledge and attitude questions, but do not connect specific knowledge about cancer to health communication variables.

None of the surveys asked the questions needed to understand how individuals use the new array of communication options to prevent cancer, support treatment, or preserve quality of life. Efforts were made, nevertheless, to include similar wordings and response options when similar items were found in other surveys that appeared to be relevant to HINTS concepts. 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.

For HINTS V, the program's management team has been careful to review the results of previous surveys conducted by the ONC to gauge the public's use of health information technologies. In an effort to reduce burden, the ONC will be contributing those items for use in the HINTS V data collection and will terminate its own data collection efforts in that area. The ONC has contributed funding to the HINTS program to serve as the sentinel data collection effort for the DHHS on items related to the use of health information and communication technologies.

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

No small businesses will be involved in this study.

#### **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. HINTS V 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, and inability to respond to a fast-changing data environment.

#### **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 June 6, 2016, Vol. 81, P. 36316. One public comment was received on June 6, 2016 which commented on expense of conducting this survey. An email response was sent on June 6, 2016 stating, “Thank you for your comments. We will take your comments into consideration.”

Comments collected from previous notifications of the survey administration through the Federal Register have generally led us to consider new, or at least more actionable, areas of coverage for the HINTS instrument. For example, comments from a representative of the Veteran’s Administration led to the inclusion of military and veteran’s status, along with the specification of VA coverage as an alternative a question about insurance status, in the demographics section of the instrument. Comments from patient advocacy groups led us to be more specific in the questions we included to assess patient engagement for patients and survivors. Both additions were fairly minor to accommodate, but have led to positive responses and publications from the research and practice communities.

The HINTS program has always relied on the broad participation of a wide variety of researchers and practitioners to develop the survey instruments. This process has historically involved multiple meetings and exchanges among involved content experts to solicit survey content across a variety of domains relevant to health communication. For HINTS V, the management team has drawn extensively from its

collaboration with the ONC as the primary operational component of the DHHS responsible for implementing strategies for connected interoperability. Conversations began with an early kick-off meeting with the appropriate ONC representatives, and continued through collaborative working sessions on early content drafts. The resulting content contains the results of this purposeful collaboration between agencies. Work with ONC was conducted with:

Vaishali Patel, PhD MPH  
Office of Planning, Evaluation & Analysis  
Office of the National Coordinator  
Department of Health and Human Services

For the development of the small pilot study of the HINTS-FDA instrument, NCI worked with FDA through:

David Portnoy PhD, MPH  
Center for Tobacco Products  
Food and Drug Administration  
301-796-9298

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

HINTS V proposes to continue including a \$2 pre-incentive as was done in HINTS III and IV based on the results of embedded methods studies conducted as part of HINTS III. HINTS III was conducted in two modes: telephone and mail. The telephone sample received an advance letter that included a \$2 incentive. The mail sample included an experiment on the impact of an incentive with a goal of determining whether a small incentive would affect mail survey response. Households were randomized to receive either \$2 or no incentive with the first questionnaire mailing. The results showed that respondents who received the incentive had a significantly higher response rate (35.8%) than those who were not offered an incentive (25.9%) (Cantor, et al, 2007). On the basis of this experiment, HINTS IV included the use of the \$2 pre-incentive in the first mailing of the questionnaire for all cycles of data collection.

Published survey methodology research confirms the HINTS incentive experiment findings. 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. In a study specific to government surveys, Shettle and Mooney (1999) concluded that incentives in government surveys provide a “decided cost advantage” in improving response rates without negatively impacting non-response bias, data quality, or respondent good will. More recently, Mercer et al. (2015) conducted a meta-analysis of existing incentive research in the published literature. They used a hierarchical regression model to analyze 55 incentive experiments containing 178 experimental conditions. These experiments on monetary incentives (prepaid or promised) were published in 1992 or later, targeted general population samples, and were employed on mail, telephone and in-person surveys. This analysis provides additional evidence for the effectiveness of pre-paid incentives in mail surveys specifically. They found that on average a \$2 prepaid incentive offered in a mail survey improves response rates by 10 points relative to offering no incentive in the same survey. Their findings indicate that prepaid incentives are especially effective in mail and telephone surveys and that this is attributable to the fact that these modes have lower baseline response rates than in-person surveys.

OMB has a history of approving incentive experimentation. For example, the Internal Revenue Service’s Individual Taxpayer Burden Survey (ITB) cross sectional mail survey currently utilizes a \$2 incentive to boost response based on experimentation approved by OMB. Newsome, et al (2012) compared a \$2 incentive to no incentive in the 2011-2012 administration of the ITB and found a 6.6 point boost in response among respondents who were recruited by mail (46.4% to 39.8). Another example of OMB-approved incentive testing is the 2011 National Household Education Surveys (NHES) Program Field Test. NHES tested incentives ranging from \$2 to \$20 and found that prepaid incentives improved response (Han, Montaquila & Brick, 2012).

While not all Federal studies include incentive payments, it is not unusual for OMB to approve of incentive payments to respondents, either prior to taking a survey or after. **Appendix H** contains an



illustrative list of just a few of the studies conducted by a single contractor on behalf of a variety of government agencies that include OMB-approved incentive payments for surveys. Incentives for other activities such as biological specimens are not included in the appendix.

#### **A.10 Assurance of Confidentiality Provided to Respondents**

All information will be kept secure to the extent allowable under the law. 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 G2** 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 I**). 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).

This study was submitted to the NCI Office of Human Subjects Review and was determined to be excluded from review. Westat has its own internal IRB under provisions specified by its multiple project

assurance plan. Westat's IRB reviewed HINTS V materials and on March 28, 2016, Westat's IRB Representative Sharon Zack indicated that this project has been granted an expedited approval. IRB documentation is provided as an **Appendix J**.

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

Very few of the HINTS research topics require collection of information on potentially sensitive questions. Respondents will be asked questions about their health, health-related risk behaviors, cancer history, and cancer treatment. 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. PII to be collected includes: sex; age; occupational status; military status; marital status; education level; whether born in the US and, if not, when arrived in the US; ethnicity; sexual orientation; race; and income. All this information will be used as variables during the analysis to identify health communication issues with specific populations. HINTS does not collect name, social security number, phone number, email address, or any type of medical record. 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 for this information collection is 2,017 hours for 4,033 respondents. The total estimate of respondent burden is 6,051 hours for 12,099 respondents over the three-year request for approval. The burden estimate is based on self-reported data from HINTS IV in which respondents reported that it took them an average of 30 minutes to complete the mail survey. The main study will be 3,500 respondents annually, 10,500 over the 3-year period, which will take approximately 30 minutes to complete. The pilot will be completed by 533 respondents annually, 1,599 over the 3-year period, and will also take 30 minutes to complete. The HINTS V instruments will be approximately the same length as other versions of HINTS. The annualized burden hours are shown in Table A12-1 below.

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 – main study (Appendix D)	3,500	1	30/60	1,750
Individual – pilot study (Appendix E)	533	1	30/60	267
<b>Total</b>	<b>4,033</b>	<b>4,033</b>		<b>2,017</b>

The total annualized cost is \$46,854.91. This cost was calculated using a wage rate of \$23.23 per hour which was obtained from the May 2015 Bureau of Labor Statistics

([http://www.bls.gov/oes/current/oes\\_nat.htm#00-0000](http://www.bls.gov/oes/current/oes_nat.htm#00-0000)) title “All Occupations,” occupation code 00-0000.

Table A12-2. Annualized cost to respondents

Type of Respondent	Total Annual Burden Hour	Hourly Wage Rate	Respondent Cost
Individual – main study	1,750	\$23.23	\$40,652.50
Individual – pilot study	267	\$23.23	\$6,202.41
Total	2,017		46,854.91

### 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

Based on the current HINTS budget, the annualized cost to the Federal Government for the proposed survey is \$799,066. Table A14-1 below, shows the annualized costs. This amount includes all direct and indirect costs of the design, data collection, analysis, and reporting phases of the study, as well as the production of public-use and restricted data sets. Contractor costs are estimated at \$600,000 annually. Contractor activities include: assistance with the development of the survey instrument, assistance with clearance documentation, development and maintenance of the system to track respondents (study management system), development of the sampling plan and the drawing of the sample, printing all materials (instrument, envelopes and return postage envelopes), conducting data collection (collating and mailing materials multiple times, managing the toll-free numbers and responding to callers, receiving and tracking survey responses, payment of incentives), data management (scanning all completed questionnaires for data capture, conducting data cleaning and editing, developing codebooks), conducting data weighting, conducting nonresponse adjustment calculations and variance estimations, development of a Methodology Report and submission of materials to NCI (including weighted datasets, codebooks, annotated survey instruments, and Methodology Report), The annual costs of Federal employees for monitoring the contract are estimated to be \$199,066. These costs are based on the Project Officer’s time

to oversee the project, staff time to support ongoing data analysis, staff time to coordinate the HINTS program, as well as additional FTEs that include several NCI staff who contributed to the content of the instrument.

Table A14-1: Annualized cost to the government

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
<b>Federal Oversight</b>					
Project Officer NCI/HCIRB	Title 42	\$182,000	25%		\$45,500
Program Coordinator NCI/HCIRB	14/5	\$123,406	50%		\$61,703
Data Analyst NCI/STRB	14/6	\$127,036	30%		\$38,111
Survey Specialist NCI/STRB	Title 42	\$153,357	20%		\$30,671
Administrative NCI/BRP	7/6	\$50,965	10%		\$5,097
Program Coordinator ONC	Title 42	\$89,924	20%		\$17,984
<b>Total Federal Oversight:</b>					<b>\$199,066</b>
<b>Contractor Cost</b>					
Data collection				NA	\$573,340
Incentives				\$0	\$26,660
<b>Total Contractor costs</b>					<b>\$600,000</b>
<b>Travel</b>				\$0	\$0
<b>Other costs</b>				\$0	\$0
<b>Total Cost to the Government</b>					<b>\$799,066</b>

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

This submission requests a reinstatement with changes that will reinstate the burden of this information collection and provide data for comparison with the previous HINTS survey data. HINTS V will use the same sampling and data collection strategy as HINTS IV. The data collection instruments for HINTS V will vary slightly from those in HINTS IV to reflect evolving government priorities (as described in detail in section A.1, page 3), although there will always be a core of at least 50% of the instrument which will remain the same as HINTS IV. The changes made to the instrument from the HINTS IV cycle can be found in Appendix L. For this first cycle of HINTS V, the survey instrument (found in **Appendix D**) has a total of 139 survey items. Of these, 26.5 items (19%) are new to HINTS. As noted in section A.2, most of these new items were developed in conjunction with the ONC and focus

on the public's interactions with a connected healthcare system. Section A.16 below describes the analytic importance of these new items in combination with traditional HINTS items. The remaining 112.5 items on the HINTS V, Cycle 1 instrument were either fielded on HINTS IV, Cycle 4 (75%) or on earlier HINTS cycles (6%). Appendix L lists all changes from HINTS 4, Cycle 4. In addition, HINTS V will include a pilot study, which increases the annual burden request from 1,750 in HINTS IV to 2,017 in HINTS V. This is an overall increase of 217 burden hours. The number of respondents for the HINTS administration has also decreased from 4,318 to 3,500 in this proposed cycle. This is a decrease of 818 respondents.

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

Analyses of HINTS V data will be guided by the research questions articulated in Section A.2. Research Questions 1-6 and 13-14 are aimed at assessing the degree to which the public uses different types of communication media to meet their cancer information needs. The analyses conducted to answer these questions will begin by tabulating weighted estimates of respondents' use of communication media in general and will explore differences in media usage by different segments of the population.

The theoretical framework presented in **Appendix K** however, suggests that simple usage statistics alone will be insufficient to meet NCI's planning needs (Nelson, et. al, 2004). Updated theories from the communication literature suggest that a continuum of usage patterns exists, which ranges from mere exposure at one end to highly interactive information seeking at the other. Communication media differ in their support for information needs along the continuum. Traditional broadcast media (television, radio, newspapers, and magazines) work best as vehicles for broad exposure. The so-called *new media* (social networking web sites, smart phones, and other emerging communication technology) support the more interactive, information-seeking behaviors at the other end. To answer Research Questions 1-6 and 13-14 accurately, analyses must take into account the full range of information consumptive behaviors along the continuum and must relate those behaviors to the full range of media options available to the modern health information consumer. Previous communication surveys have concentrated primarily on exposure

variables at one end. HINTS is the first survey to provide in-depth data on the specific ways in which health information consumers use all types of media to meet cancer information needs along the full breadth of the cancer control continuum.

The theoretical framework underlying HINTS also incorporates data points suggested by modern “stage” theories of health behavior change. The most critical of these is the Precaution-Adoption model proposed by Dr. Neil Weinstein of Rutgers University, a consultant on HINTS 2003 and 2005 (Weinstein, Sandman, 2002). Research Questions 7-12 are designed to produce prevalence estimates of cancer prevention behaviors as practiced by adults in the United States. The analyses conducted in support of these questions will use Dr. Weinstein’s theoretical model to explore and substantiate the structural determinants of specific cancer prevention behaviors. Results will contribute to the overall knowledge base in health education and will provide greater specificity to NCI’s evidence-based approach to communication.

The new items to be included in HINTS V, represented by research questions 15-20, should provide an early window into the adoption of new aspects of a digitally supported healthcare system both for the general public and selected populations of cancer patients / survivors. Weighted descriptive analyses will be generated in collaboration with researchers at the ONC and other components within the NCI to provide a rapid assessment of who is being affected by these changes, and what implications the changes may imply for adaptive communication strategies. These new items will also provide a platform for behavioral scientists and communication specialists to explore for trends in the ways in which technology changes are influencing patient behavior. These new items should also work well when integrated with other public health surveys using common data elements; that is, the trended items will become part of the NIH “Big Data to Knowledge” approach toward using analyses that emphasizes the dynamic, integrative, and combinatorial value of synthesized trends (Hesse, Moser, Riley, 2015).

Data analysis and publication of results for HINTS by both NCI and outside researchers has been ongoing and prolific. To date, 2,873 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 266. 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 HINTS website: <http://hints.cancer.gov/research.aspx>

As noted earlier, HINTS V will consist of 3 cycles of data collection. Prior to each cycle of data collection, HINTS will submit the final data collection instrument for that cycle for OMB review. Once OMB has approved the data collection instrument, the cycle will involve the collection of mail data, data cleaning and weighting, and the development of a data file. Data analysis will start on the data from each cycle as it is finalized. The anticipated schedule is outlined in Table A16-1.

Table A16-1. HINTS V Project Schedule

<b>Activity</b>	<b>Time Schedule</b>
<b>Cycle 1 and Pilot Study</b>	
Field Period	0-2 months after OMB approval
Data cleaning and weighting	6 months after OMB approval
Analysis started	7 months after OMB approval
<b>Cycle 2</b>	
Submission of instrument to OMB	9 months after OMB approval
Field period	11 months after OMB approval
Data cleaning and weighting	15 months after OMB approval
Analysis started	16 months after OMB approval
<b>Cycle 3</b>	
Submission of instrument to OMB	18 months after OMB approval
Field period	20 months after OMB approval
Data cleaning and weighting	24 months after OMB approval
Analysis started	25 months after OMB approval
Publications and presentations	Starting 9 months after OMB approval and continuing



Activity	Time Schedule
	throughout the rest of the HINTS 4 period

**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.