

Supporting Statement A For:

Health Information National Trends Survey 4 (HINTS4)

(NCI)

OMB No: 0925-0538, Expiry Date 3/30/2009

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**This submission is a Reinstatement with Changes.
This submission could not be submitted prior to the expiry date due to a change in
methodology and a delay in awarding contract.**

Yellow Highlights indicate changes from the 2007 submission.

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A. JUSTIFICATION

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 4 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. 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 4 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).

History of HINTS 1 through 3 (2001-2009)

The development and communication of public messages about cancer prevention, detection, diagnosis, treatment, and survivorship require comprehensive understanding of individuals’ access to cancer related information; perceived trust in information sources; cancer- and health-related knowledge; and factors that facilitate or hinder communication. In response to the critical mission of informing dissemination and communication of cancer information to the public and to support related programmatic efforts, NCI funded the first Health Information National Trends Survey (HINTS) in June 2001 (OMB #0925-0507, Exp. Date: 8/31/03). NCI, together with its study contractor Westat, administered the first HINTS, a cross-sectional survey of the U.S. civilian, noninstitutionalized, adult population. The purpose of funding a national probability survey to assess health communication processes is to provide communication researchers with population estimates of the prevalence of cancer-relevant knowledge, attitudes, and information-seeking behaviors in the U.S. adult population (18+). Through each administration of HINTS, survey content is aligned with emerging theories of media usage (Viswanath and Finnegan, 1996), risk information processing (Fischhoff, Bostrom, and Quadrel, 1993; Croyle and Lerman, 1999),

behavior change (Weinstein, 1993), health communication (Glanz, Lewis, and Rimer, 1997), and the diffusion of innovations (Rogers, 1995), to expand the scientific knowledge base in health communication and support evidence-based planning of population-level interventions.

The first round of HINTS (HINTS 1), administered in 2002 and 2003, used a probability-based sample, drawing on random digit dialing (RDD) telephone numbers as the sample frame of highest penetration at that time. Data were collected from 6,369 respondents. HINTS 1 yielded a response rate of 33 percent, which was lower than anticipated but consistent with declining response rates for RDD studies in the field of survey research overall (Singer, Van Hoewyck, & Maher, 2000).

In an effort to address diminishing response rates, the second cycle of HINTS (HINTS 2), conducted in 2005, included embedded methodological experiments to compare data collected by telephone with data collected through the Internet. In addition, this field study explored the impact of varying levels of incentives on response rates. Even though data were collected from 5,586 respondents, the overall response rate for HINTS 2 was low at 24 percent. Although decreasing telephone response rates have been experienced across the survey industry (Dillman, 2000; Curtin, et al., 2005), it had been expected that providing respondents with an Internet alternative, a monetary incentive for nonresponders, and making nonresponse conversion a priority would reduce the impact of declining response rates. However, this did not prove to be the case.

HINTS 3, conducted in 2008, included additional priorities: to provide guidance for strategies to increase response and to undertake a thorough assessment of the reasons for nonresponse, including the development of a mixed mode design and conducting research on the mailing materials. A series of focus groups were conducted on the letters sent to respondents and the cover of the mail questionnaire. The goal of the focus groups was to find the best way to motivate respondents to complete the survey. The mixed-mode data collection design employed dual sampling frames, both RDD and Addressed Based Sampling

(ABS) frames, and provided a nationally representative sample in each. An RDD telephone survey and a mail questionnaire were implemented as the two modes including telephone follow up of a subsample of the nonrespondents. RDD respondents received the full questionnaire administered via computer-assisted telephone interview (CATI). Data were collected from 4,092 respondents via CATI and 3,582 respondents via mail for a total of 7,674 respondents. HINTS 3 results showed that the CATI interview had an overall response rate of 24 percent while the mailed survey had an overall response rate of 31 percent. The embedded experiment on response rate that was included in the mail pilot test revealed that the highest response rate was obtained by including a \$2 incentive and using an express postal service; thus, the incentive and express mail were also used in the main study.

Priorities for HINTS 4

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. Components of the HINTS website have been designed to address the needs of data users. In an effort to obtain information regarding audience reach and satisfaction with the HINTS program among a variety of different stakeholders, NCI supported an evaluation of the HINTS program in 2010. Focus groups and interviews with data users and results users in various positions, including academics, cancer control planners, graduate students, CDC staff members, and cancer center communication directors were conducted to

provide valuable data on current and future uses of HINTS data and program products. See **Appendix A** for the recommendations resulting from the evaluation.

HINTS 4 draws upon the recommendations following from this evaluation and lessons learned from prior iterations of HINTS to continue the work of the previous rounds of HINTS, while employing some new strategies. Based on the higher response rates for the mail survey (over the RDD survey) in HINTS 3, a single-mode mail survey will be implemented with the inclusion of the \$2 incentive. The use of express mail, which was shown to be effective in HINTS 3 follow-up mailings, will also be employed. To try to increase participation by Hispanic respondents, all materials will be translated and respondents will have the option of completing the mail questionnaire in Spanish. To more quickly address emerging issues in the field of health communication while still maintaining the ongoing measurement of trends, HINTS 4 will include four data collection cycles over the course of 3 years. The instrument for each data collection cycle will include a core module of trended items in addition to special topic modules to be implemented in only some of the cycles, increasing capacity of the HINTS instruments to include additional topics and measures. The overall sample size for all four cycles of HINTS 4 combined will be approximately 14,000 respondents which is about twice the size of previous rounds of HINTS data collections.

As with previous rounds, HINTS 4 will include embedded methodological experiments designed to maximize response rates, reduce bias, and obtain the highest quality data. It is anticipated that these experiments will inform not only future HINTS data collections, but also the larger survey methods field. Experiments will include variations in the respondent selection process, the formatting and structure of questionnaire items administered by mail, and specific activities targeting Spanish-speaking populations.

A.2 Purpose and Use of the Information

HINTS 4 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

The HINTS 4 instruments will potentially include questions from the following constructs:

| | | |
|--------------------------------------|--|--------------------------------|
| Affective Forecasting | Environmental Health Information | Patient satisfaction |
| Alcohol | Seeking | Patient-provider communication |
| Ambiguity aversion | Environmental Health Knowledge | Perceived Discrimination |
| Attention to health information | Environmental Health Perception | Perceived vulnerability |
| Autonomy Support | Environmental Health Seeking Behavior | Personal Behaviors |
| Avoidance | Exposure to support Resources | Physical Activity |
| Behavior change | Exposures in the home | Pluralistic ignorance |
| Bodily Pain | Family History | Prostate Cancer |
| Bracing | Food Safety and Applied Nutrition | Quality of Life |
| Breast cancer | Food Security | Radiation |
| Built Environment | Genomics | Religiosity and Spirituality |
| Cancer perceptions | Health Behavior | Secondhand Smoke |
| Cancer related knowledge | Health Care | Self-affirmation |
| Cancer Risk Perceptions | Health information seeking | Skin cancer |
| Cancer Screening Knowledge | Health Information Technology | Sleep Quality |
| Cancer survivorship | Health literacy | Social Support |
| Caregiver Preparedness | Health Self-Efficacy | Sun Safety |
| Cervical Cancer | Health status | Tobacco: Behavioral Tradeoff |
| Chemical Exposures | Implicit theories | Tobacco Use |
| Clinical Trial | Information Seeking | Tobacco: Cessation |
| Colorectal cancer | Information-Seeking about Medical | Tobacco: Implicit Theories |
| Comorbidity | Products and Foods | Tobacco: Intentions |
| Consideration of future consequences | Insurance status | Tobacco: Pluralistic Ignorance |
| Demographics | Internal Process Data | Tobacco: Product Packaging |
| Depression | Lung cancer | Tobacco: Products |
| Dietary Assessment | Media exposure to contradictory health | Tobacco: Regulation |
| Endocrine Disruptors | Information | Tobacco: Risk Perception |
| Environment and Cancer | Mental Models of Cancer | Trust and Mistrust Items |
| Environmental Exposure | Mental Models of Screening | |
| Risk Perception | Numeracy (Health) | Use of Technology |

Nutrition
Occupational Exposures
Patient Activation

Values/Aspirations
Water Source
Weight Stigma Concerns
Weight/Weight Loss
Worry

The instrument for each of the four cycles of data collection cycles will include some core items that will appear in each data collection cycle, but other survey items will vary by cycle. A comprehensive list of potential items is attached as **Appendix B1**. Each data collection instrument will draw from the items on this comprehensive list to create a survey instrument that will take respondents no longer than 30 minutes to complete. As discussed on the November 29, 2010 conference call between OMB, NIH and NCI, each specific data collection instrument will be submitted to OMB for review prior to the cycle in which it is to be used. No data collection will take place until OMB approval has been granted for each specific data collection instrument. The final instrument for the first cycle of data collection is attached as **Appendix B2**. See **Appendix C** for minutes of the November 29, 2010 conference call.

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?

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 D** for the list of 2020 objectives and sources.
- **U.S. Food and Drug Administration (FDA):** Colleagues at the FDA have developed and contributed a series of items to HINTS 4 to assess public perceptions of and understanding of direct

to consumer advertising. FDA is interested in using HINTS to better understand reactions to messaging around direct to consumer advertising.

■ **Office of the National Coordinator (ONC):** The ONC has collaborated with NCI to designate content for inclusion in HINTS 4 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.

■ **Centers for Disease Control and Prevention:** Colleagues at CDC have proposed inclusion of items to assess individuals' perceptions of and knowledge about genetic risk and are interested in using HINTS to track population awareness, knowledge, and perceptions of genetic risk.

■ **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.

Methods of Dissemination

As with the first three rounds of HINTS,¹ data from HINTS 4 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 HINTS 4 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. 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/>) that allows interaction with the data (e.g., graphical representations of frequency data can be displayed easily) and can be downloaded for

¹ HINTS 1: OMB #0925-0507, Exp. Date: 8/31/03, *Federal Register* 60-Day Notice published December 21, 2000, Vol. 65, pages 80444-80445; HINTS 2: OMB #0925-0538, Exp. Date 11/30/2007, *Federal Register* 60-Day Notice published April 13, 2004, Vol. 69, pages 19436-19437; HINTS 3: OMB #0925-0538, Exp Date 11/30/08, *Federal Register* 60-day Notice published October 26, 2006, Vol. 71, pages 62597-62598.

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 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 list of publications of HINTS data, see **Appendix E**.

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 F1** 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. **Appendix G** details the major sources reviewed.

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.

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 4 will be the fourth 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.

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 submission to OMB was published on April 22, 2011 (76 FR 22714). One public comment was received on April 23, 2011 which commented on the number of previous surveys and expense. An email response was sent on April 25, 2011, stating, “Thank you for your comments. We will take your comments into consideration.”

The HINTS program has always relied on the 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. One drawback of this particular approach to participation in and coordination of this effort is that it lacks transparency, is burdensome, time-consuming, and inefficient. For HINTS 4, NCI developed HINTS-GEM, an online application to enable technology-mediated social participation in survey development. HINTS-GEM is a dynamic web-based database that enables researchers to use common measures with the eventual goal of comparing and exchanging harmonized data. HINTS GEM enables a broad community of researchers and practitioners to develop and refine a set of survey items for inclusion in HINTS. The resulting systematic and transparent process thus draws upon collective, multidisciplinary expertise to ensure that future iterations of HINTS include measures that are of greatest interest to the practitioners and scientists who use HINTS data in their work. HINTS-GEM provides an excellent example of how electronic infrastructure can be employed to leverage the “wisdom of the crowd” to create a timely and high-quality surveillance tool. By bringing researchers together at the inception of a survey and making use of HINTS-GEM to keep the community updated about data collection and availability over time, we hope that HINTS-GEM will do more than help NCI build a better HINTS – HINTS-GEM may also serve to stimulate collaboration around and scientific discovery via HINTS research.

A.9 Explanation of Any Payment or Gift to Respondents

We are proposing to include 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).** The 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 3 used a \$2 incentive as proposed for HINTS 4 (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 F2 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).

This study will be submitted to the NCI Office of Human Subjects Review. Westat has its own internal IRB under provisions specified by its multiple project assurance plan. Westat's IRB reviewed HINTS 4 materials and on **November 11, 2010**, Westat's IRB Chairperson, **Kerry Levin** indicated that this project has been **provided an expedited approval**. IRB documentation is provided as an **Appendix I**.

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. 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 hour burden for HINTS 4 is shown in Tables A12-1 and A12-2 below. The mail questionnaire will take approximately 30 minutes (.5 hours) to complete. This estimate is based on self-reported data from HINTS 3: respondents reported that it took them an average of 30 minutes to complete the mail survey. We anticipate the HINTS 4 instruments to be approximately the same length as HINTS 3.

The total estimate of respondent burden is 1,767 hours annually for each of the first two cycles of data collection and 1,750 hours for data collection cycles 3 and 4. This amounts to an annual estimate of 7,033 hours and approximately 21,099 hours between 2011 and 2014 (3 year information collection period). The annualized cost is calculated with a wage rate of \$21.61 per hour for 7,033 burden hours² and is estimated to be \$152,005. Over the course of 3 years, the total cost is estimated to be \$456,014.

Table A12-1. Estimate of respondent hour burden

| Data Collection Cycle | Type of respondent | Number of respondents | Frequency of response | Average time per response Minutes/Hour | Annual hour burden |
|------------------------------|---------------------------|------------------------------|------------------------------|---|---------------------------|
| Cycle 1 | Mail survey | 3,533 | 1 | 30/60 | 1,767 |

² National Compensation Survey, All United States, December 2008 – January 2010. *Table 4: Full-time private industry workers: Mean and median hourly, weekly and annual earnings and mean weekly and annual hours.* Bureau of Labor Statistics, US Department of Labor.

| | | | | | |
|----------------|-------------|---------------|---|---------------|--------------|
| | | | | (.5) | |
| Cycle 2 | Mail survey | 3,533 | 1 | 30/60 (.5) | 1,767 |
| Cycle 3 | Mail survey | 3,500 | 1 | 30/60 (.5) | 1,750 |
| Cycle 4 | Mail survey | 3,500 | 1 | 30/60 (.5) | 1,750 |
| Total | | 14,066 | | | 7,033 |

Table A12-2. Annualized cost to respondents

| Data Collection Cycle | Number of respondents | Frequency of response | Average time per response | Hourly Wage Rate | Respondent cost |
|------------------------------|------------------------------|------------------------------|----------------------------------|-------------------------|------------------------|
| Cycle 1 | 3,533 | 1 | .5 | \$21.61 | \$38,184.87 |
| Cycle 2 | 3,533 | 1 | .5 | \$21.61 | \$38,184.87 |
| Cycle 3 | 3,500 | 1 | .5 | \$21.61 | \$37,817.50 |
| Cycle 4 | 3,500 | 1 | .5 | \$21.61 | \$37,817.50 |
| Total | | | | | \$151,004.74 |

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 total cost to the Federal Government for the proposed survey is \$3,779,618 for the 4 year period from September 24, 2010, to September 23, 2014. The annualized cost is approximately \$944,905 which amounts to \$2,834,714 over a three year time frame. 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. The annual costs of Federal employees for monitoring the contract are estimated to be \$287,250. These costs are based on 50 percent of the Project Officer's time, 75 percent of an individual's time to support ongoing data analysis, 75 percent of individual's time to coordinate the HINTS program, as well as an additional .5 FTE that includes several NCI staff who contributed to the content of the instrument.

A.15 Explanation for Program Changes or Adjustments

This submission represents a reinstatement with changes that will provide data for comparison with the previous HINTS survey data. Previous HINTS data collections have had between 5,000-7,000 respondents every other year. HINTS 4 is planning for 14,066 respondents in 4 data collection cycles over the course of 3 years. Each data collection cycle will have up to 3,533 respondents. This is an increase in burden from the previous submission due to a slight increase in the number of respondents and an increase in the estimated time per response.

Other changes in this submission that are new include having 4 data collection cycles rather than on a biennial schedule as was the past. This study design will allow HINTS to more quickly address emerging issues in the field of health communication, maintain the ongoing measurement of trends, and include additional topics and measures. Additionally, a Spanish version of the questionnaire is being developed to accommodate Hispanic respondents. As with previous rounds, HINTS 4 will include embedded methodological experiments designed to maximize response rates, reduce bias, and obtain the highest quality data. Experiments will include variations in the respondent selection process, the formatting and structure of questionnaire items administered by mail, and specific activities targeting Spanish-speaking populations.

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

Analyses of HINTS 4 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 J** 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.

Data analysis and publication of results for HINTS by both NCI and outside researchers has been ongoing and prolific. To date, 2,574 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 135. 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 E**.

As noted earlier, HINTS 4 will consist of 4 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 4 Project Schedule

| Activity | Time Schedule |
|---------------------------------|---|
| Cycle 1 | |
| Field Period | 0-2 months after OMB approval |
| Data cleaning and weighting | 6 months after OMB approval |
| Analysis started | 7 months after OMB approval |
| Cycle 2 | |
| 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 |
| Cycle 3 | |
| 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 |
| Cycle 4 | |
| Submission of instrument to OMB | 27 months after OMB approval |
| Field period | 29 months after OMB approval |
| Data cleaning and weighting | 33 months after OMB approval |
| Analysis started | 34 months after OMB approval |
| Publications and presentations | Starting 9 months after OMB approval and continuing 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.

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