

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The National Cancer Institute (NCI) has the vital mission of facilitating the process by which cancer research is communicated to the public. The task of collecting data relevant to cancer communication falls on 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.

To address these goals, NCI funded the first Health Information National Trends Survey (HINTS) in June 2001 (OMB #0925-0507, Exp. Date: 8/31/03; *Federal Register* 60-Day Notice published December 21, 2000, Vol. 65, pages 80444-80445). NCI, together with its study contractor Westat, administered the first of what is intended to be an ongoing, cross-sectional survey of the U.S. civilian, noninstitutionalized, adult population. The purpose of funding a biennial national probability survey to assess health communication processes was 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+). By aligning the content of the survey 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), population scientists should not only be in a more effective position for planning population-based interventions but they should also be in a position of using data from the survey to refine the scientific knowledge base.

The priorities for HINTS 2007 are (1) to preserve the methodological integrity of the survey and (2) to implement procedures in anticipation of the increasingly difficult survey environment related to telephone surveys and random digit dial (RDD) surveys in particular.

The Public Health Services Act outlines the research and information dissemination mission of the NCI. Appendix A contains the full text of 42 USC, Sections 285a, 285a-1.1, and 285a-1.3. HINTS 2007 is specifically designed to support this mission by providing a means to address health communication issues that have not been adequately studied through other data collection efforts. NCI 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 2007

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).

A.2 Purpose and Use of the Information

HINTS 2007 will provide NCI with a comprehensive assessment of the American public's current access to, and use of, information about cancer, that will include cancer prevention, early detection, diagnosis, treatment, and prognosis. 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. HINTS 2007 is intended to be the foundation of NCI's effort to build on the opportunities presented by a national shift in communication context, and by so doing, improve the Nation's ability to reduce the national cancer burden.

A.2.1 Research Questions

The analyses enabled by the survey will allow NCI and the cancer communication community to refine its communication priorities 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:** To what extent is access or lack of access to different sources of health information associated with cancer knowledge or behaviors?
- **Research Question 3:** 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 4:** How trustworthy are the sources of health information perceived to be, and how satisfied are respondents with information access and content?
- **Research Question 5:** 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 6:** How are cancer prevention behaviors related to sources of information and their use? and
- **Research Question 7:** How do people want to get information about cancer-related issues?

In addition, the purpose of the procedures in the HINTS 2007 is to assess the differential response rates across two sampling frames, the comparability of the samples, and the comparability of survey response distributions and costs. The evaluation questions related to the dual-frame, dual-mode design of the survey can be found in Appendix B.

A.2.2 Audiences for Data and Results

The authors of the Healthy People 2010 initiative argued that effective health communication strategies are becoming “increasingly recognized as a necessary element of efforts to improve personal and public health.”¹ 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. For more detailed information about stakeholders, see Appendix C.

- **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.

A.2.3 Methods of Dissemination

As with the first two rounds of HINTS,² data from HINTS 2007 will be made available for public use following the removal of all identifying information, such as telephone numbers or names. Data files will be prepared in accordance with standards for protecting the confidentiality of the participants. HINTS 2007 data will then be made available through various mechanisms as described below.

- **Reports.** NCI will prepare descriptive reports summarizing the data in terms of cancer knowledge, preventive behavior, and communication preferences. These reports will be made available in hard copy and over the Internet on the HINTS web site (<http://cancercontrol.cancer.gov/hints/>).
- **Data.** The data files and documentation 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. In addition to the raw data files, NCI will add HINTS 2007 data to the electronic codebook (found at <http://cancercontrol.cancer.gov/hints/>) that allows interaction with the data (e.g., graphical representations of frequency data can be displayed easily) and can be downloaded for reports and manuscripts.
- **Presentations and Publications.** NCI staff, as well as researchers in cancer and health communication who access the raw data, will prepare presentations that will be 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 will be summarized and submitted to peer-reviewed research journals such as the *American Journal of Public Health*, *Journal of the*

¹ See <http://www.health.gov/HealthyPeople/Document/HTML/volume1/11HealthCom.htm>.

² HINTS 2003: OMB #0925-0507, Exp. Date: 8/31/03, *Federal Register* 60-Day Notice published December 21, 2000, Vol. 65, pages 80444-80445; and HINTS 2005: OMB # 0925-0538, Exp. Date 11/30/2007, *Federal Register* 60-Day Notice published April 13, 2004, Vol. 69, pages 19436-19437.

A.3 Use of Information Technology and Burden Reduction

Computer-assisted telephone interviewing (CATI) systems will be employed for half of the HINTS 2007 data collection activities. The most important features of the CATI system that reduce burden are described below. These features of CATI not only reduce respondent burden, but also enable efficient use of study resources and timely capturing of information during the field period.

- **Sampling.** The CATI will be programmed to identify eligible household members and sample respondents for interviews. This reduces the need for separate screening and interviewing calls, reducing respondent burden.
- **Scheduling.** The CATI scheduler will be used to route telephone numbers to interviewers, maintain a schedule of callback appointments, and reschedule unsuccessful contact attempts to an appropriate day and time. This system also allows the assignment of random subsets of the total sample to any experimental conditions embedded in the data collection.
- **Skip Patterns.** The CATI system will automatically guide interviewers through the complex skip patterns in the questionnaire, reducing the potential for interviewer error and shortening the questionnaire administration time.
- **Multiple Languages.** The HINTS instrument will be translated into Spanish for administration to Spanish-speaking respondents. The CATI system allows interviewers to change between English and Spanish language versions with a single keystroke.
- **Receipt Control.** The CATI system will provide for automatic receipt control in a flexible manner that will be used to produce status reports that allow ongoing monitoring of the survey's progress.

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

During the development of the HINTS 2007 instrument, 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 D details the major sources reviewed.

Results of the source review indicated that no existing survey adequately covered the topic areas central to HINTS 2007. Items from the existing Internet surveys (e.g., UCLA, Pew Charitable Trust, Georgia Tech, and Harris Poll) covered topics related to general Internet usage, but did 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) obtained data about respondents' behaviors and contained a limited number of knowledge and attitude questions, but did 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 2007 is intended to be the third round of this biennial, 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

Notice of this study was published in the *Federal Register* on October 26, 2006 (Volume 71, Number 207, Pg. 62597-62598). One comment from the public was received expressing concern that a third round of HINTS data collection is unwarranted because data were provided in previous rounds. While it is true that some questions are repeated on every round of HINTS data collection, this study is designed to provide trend data that can be used to determine changes in the way people get cancer information over time. In addition, each round of HINTS includes new questions that have not been asked before in order to provide information that is relevant and time sensitive. For example, HINTS 2007 will include questions about the newly announced human papillomavirus or HPV vaccine to gauge the public's awareness and response to this unique development in cancer control. For these reasons, it is important that the HINTS survey be conducted on a biennial basis as originally designed. In response to the comment received, NCI will ensure that descriptions of HINTS discuss that HINTS is a trends survey designed to look at changes over time in addition to information on emerging topics.

HINTS 2007 builds on the input of many experts in the field of cancer and health communication research that were consulted during the development of previous versions of the HINTS questionnaire. In addition, substantial efforts were made to consult with additional content experts and experts in survey

methodology, both internal and external to the agency, on issues related to the survey design plan and questionnaire development. A list of individuals who provided their expertise in specific areas of cancer knowledge and survey methodology can be found in Appendix E.

A.9 Explanation of Any Payment or Gift to Respondents

Incentive payments to survey respondents have been common practice for several years. Theoretical frameworks such as the social exchange theory (Dillman, 1978), the norm of reciprocity (Gouldner, 1960), and economic exchange (e.g., Biner and Kidd, 1994) all describe and document the effectiveness of incentives in gaining cooperation.

For the telephone sample, letters sent to households before the initial screening interview will include a \$2 incentive (see Appendix M). Refusal conversion letters sent to households from the RDD sample selected for refusal conversion will include a \$2 incentive. This differs from the plan initially submitted to OMB in March 2007 in that the refusal conversion incentive has been reduced from \$5 to \$2. The study conducted for HINTS I found that using an identical plan (i.e., \$2 at pre-note and \$2 at refusal conversion) does increase the response rate. Both incentives were found to have independent effects (Rizzo, et al., 2004).

For the mail sample, the pilot and main field study will include an experiment on the impact of an incentive included in the first mailing of the questionnaires (see Appendix N). Households selected to receive the mail questionnaires will be randomized to receive in the initial mailing of the questionnaire with either no incentive or a \$2 household incentive. The goal of this experiment is to determine whether a small incentive can affect mail survey response. The intent is for the incentive to increase the number of people who read the letter and distribute the survey to all eligible members of the household. This differs from the plan initially submitted to OMB in March 2007 in that the mail incentive experiment has been employed in the first, rather than the second, mailing of the questionnaire. While it is the case that substantial evidence exists on the effectiveness of incentives for mail surveys, there is no evidence of how it works in the present context. The research question that the experiment would test is whether the incentive improves rate of return from all members of the household, even those that did not open the package.

A.10 Assurance of Confidentiality Provided to Respondents

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 confidential treatment of records maintained by a Federal agency according to either the individual's name or some other identifier. NCI published a System of Records notice in the *Federal Register* on Thursday, September 26, 2002 (Vol. 67, No. 187,

pp. 60776-0779). All members of the HCIRB and staff working with HINTS data will adhere to the provisions stipulated within that announcement (see Appendix F).

The CATI survey instrument includes a statement of confidentiality in the introductory language read to sampled persons. HINTS 2007 will collect and maintain a few personal identifiers during the household screening process to determine individual eligibility. However, none of the identifiers (with the exception of gross geographical measures) will be associated with data collected. Because of the RDD sample, perhaps as much as 50 percent of the sample will have no identifier (such as address) associated with the telephone number. Identifying information that is obtained will be destroyed upon completion of the study. Electronic storage areas within the survey instruments will be reformatted using a standard security erase routine and paper documents will be shredded and disposed of securely.

The mail survey will include a numeric identifier associated with the household to which the survey was sent. No names are being requested on the instrument and the data will not include the mailing address.

Westat, the study contractor, has its own policy and procedures regarding assurance of confidentiality and a pledge that all employees must sign (see Appendix G). Westat provides all safeguards mandated by Privacy and Confidentiality Acts to protect the confidentiality 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).

The NIH Office of Human Subjects Review has reviewed this study and has determined that it is exempt from NIH Institutional Review Board (IRB) review. Westat has its own internal IRB under provisions specified by its multiple project assurance plan. Westat's IRB reviewed HINTS 2007 materials and on April 26, 2006, Westat's IRB Chairman, Thomas W. McKenna indicated that the project is exempt from IRB review under the provisions of 45 CFR §46.101(b)(2). IRB documentation is provided as an Appendix H.

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.

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 confidentiality of their responses and of the voluntary nature of their participation in the survey or any of its components, including specific questions that they may prefer not to answer. Furthermore, participants' names will not appear on any study documents containing data. A crosswalk between study ID and participant name will be kept in a secured electronic file and will be accessible only to those working on the study. Electronic interview data will be identified by the unique study ID only. 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 total estimate of respondent burden in the original submission was 3,731 hours. The burden estimate is revised to 3,556 hours for the following reasons:

- Response rates will be the comparison measure for the different treatments in the RDD advance materials test. Consequently, it is not necessary to conduct additional screener interviews with RDD respondents in order to evaluate the advance materials test. Eliminating these additional screener interviews reduces the response burden estimate by 37 hours.
- An incorrect value for the average number of adults per household was used in the original calculation of the response burden for the address sample. The address-sample response burden has been recalculated. The original burden estimate was based on 3,500 completed mail questionnaires and 457 completed telephone follow-up interviews, totaling 1,434 burden hours. The revised estimate of burden for the address sample is based on 2,983 completed mail questionnaires and 517 completed telephone follow-up interviews, totaling 3,500 complete responses and 1,296 burden hours.

Revised estimates of hour burden and costs to respondents for HINTS 2007 are shown in Revised Table A-1. The RDD household screener will take approximately 5 minutes (.0833 hours) to complete. The RDD extended interview will take approximately 25 minutes (.4167 hours) to complete. The mail questionnaire will take approximately 20 minutes (.3333 hours) to complete. The total estimate of respondent burden is 3,731 hours. The cost to the respondents for the total burden is estimated to be \$56,896, that is, \$16 per hour for 3,556 burden hours.

Revised Table A-1. Estimate of respondent hour burden for HINTS 2007

Type of respondent	Estimated number of respondents	Frequency of response	Estimated number of responses	Average hours per response	Annual hour burden	Respondent cost**
Pilot RDD screener only	133	1	133	.0833	11	\$176
Pilot RDD screener and interview	200	2	400	.2500*	100	\$1,600
Pilot mail survey	640	1	640	.3333	213	\$3,408
RDD screener only	2,333	1	2,233	.0833	186	\$2,976
RDD screener and interview	3,500	2	7,000	.2500*	1,750	\$28,000
Mail survey	2,983	1	2,983	.3333	994	\$15,904
Telephone screener only for mail followup	517	1	517	.0833	43	\$688
Telephone screener and interview for mail followup	517	2	1,034	.2500*	259	\$4,144
Total	10,823		14,940		3,556	\$56,896

* $(0.833 + 0.4167) / 2 = 0.2500$.

**Hourly wage rate = \$16.00.

Drafts of the screener and survey instruments can be found in Appendixes I and J. The current version of the RDD extended questionnaire is over inclusive and clearly longer than the anticipated 25 minutes per respondent listed in the burden estimate (see Appendix J). This draft version is intended to demonstrate the entire range of potential questions for HINTS 2007. During the next few months and during the field test, we intend to reduce the size of the instrument to be consistent with the burden estimates included here. The mail version of the instrument will have complicated skip patterns and will eliminate the sex-specific questions. In addition, we anticipate the likelihood that a written survey will take longer to complete than a telephone survey. Therefore, we will further reduce the number of items included on the mail survey, as necessary, to reduce the respondent burden to the estimate stated above. Finalized instruments will provide to OMB.

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 \$1,516,896 for the 24-month period from April 10, 2006, to April 30, 2008. The annualized cost is approximately \$758,448. 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 costs of Federal employees for monitoring the contract are estimated to be \$210,000. 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, 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 study represents a new collection of information that will provide data for comparison with the previous HINTS 2003 and 2005 surveys.

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

Analyses of HINTS 2007 data will be guided by the seven research questions articulated in Section A.2.1. Research Questions 1, 2, 3, and 7 are aimed at assessing the degree to which the public uses different types of communication media to meet its 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. 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* (web sites, email, and Personal Digital Assistants) support the more interactive, information-seeking behaviors at the other end. To answer Research Questions 1, 2, 3, and 7 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. This survey is the first 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 continuum.

The theoretical framework underlying HINTS 2007 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. Research Questions 4, 5, and 6 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. Table A-2 lists the scheduled timeline for conducting analyses and reporting results.

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.

Table A-2. Project time schedule

Study activity	Time schedule after OMB approval
Pilot tests	< 1 month
Field test	1 month
Revision of study instruments	2 months
Main data collection	3-7 months
Data coding	7-9 months
Data delivery	9 months
Data dissemination	11 months
Final report	11 months

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

NCI is not requesting an exception to the certification requirements.

