

Supporting Statement A for Request for Clearance:
NATIONAL HEALTH INTERVIEW SURVEY

OMB No. 0920-0214

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Supporting Statement

NCHS National Health Interview Survey

This request is to extend data collection for the core National Health Interview Survey (NHIS) and to modify selected sections of the NHIS for the next three years (OMB 0920-0214). The NHIS is a major ongoing source of information on the health of the civilian, noninstitutionalized population of the United States. This request includes:

- Continuing the core questions in the Family, Sample Adult and Sample Child sections.
- Continuing the immunization record check follow-up study.
- Continuing the disability split sample study with new questions.
- Adding additional questions on cancer, occupational injury, epilepsy, and child mental health.
- Cycling out supplementary questions on carbon monoxide detectors, stroke, arthritis, health care workers, and the use of the internet to learn about health information or to communicate with health care providers.
- Continuing the reinterview survey for quality assurance purposes.
- Permission to modify selected sections of the 2011 and 2012 surveys through a nonsubstantive change clearance request. For example, the 2012 NHIS will include supplementary questions on complementary and alternative medicine, last collected in 2007.

A. Justification

1. Circumstance Making the Collection of Information Necessary

Background

The NHIS is conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), to comply with the NCHS mandate under 42 USC 242k (Attachment 1) to collect, on an annual basis, statistically valid data on the amount, distribution, and effects of illness and disability in the population and on the utilization of health care services for such conditions. NHIS data are used widely throughout the Department of Health and Human Services (DHHS) to monitor trends in illness and disability and to track

progress toward achieving many of the Healthy People objectives for the nation. The data are also used by the public health research community for epidemiologic and policy analysis of such timely issues as characterizing those with various health problems, determining barriers to accessing and using appropriate health care, and evaluating the impact of changes in federal health programs.

In accordance with the 1995 initiative to increase the integration of surveys within DHHS, respondents to the NHIS serve as the sampling frame for the Medical Expenditure Panel Survey (MEPS). This survey (OMB# 0935-0018) is conducted by the Agency for Healthcare Research and Quality. MEPS uses completed interviews from the NHIS to identify and select the desired sample, contacts that sample to collect additional data, and combines their survey data with the original NHIS data. These procedures reduce survey costs, reduce overall respondent burden, and increase the amount of data available for analysis.

The NHIS has been conducted every year since 1957. The current design of the NHIS was fully implemented in 1997, and consists of a standard Basic or Core Module, covering basic health topics and demographic characteristics, that are repeated every year. In addition to the Core Module, each year supplementary questions or modules may be included. For example, the 2010 NHIS will include supplementary questions or Topical Modules on cancer, occupational injury, epilepsy, and child mental health. The 2012 NHIS will include supplementary questions on complementary and alternative medicine. Other topics are rotated in and out of the annual NHIS depending on funding availability and data requirements of federal programs such as Healthy People 2020.

The NHIS serves a critical role in providing information for monitoring and evaluating the performance of public health programs. The NHIS meets this need in several ways. First, the NHIS provides information on the overall health status of the U.S. population and its health needs, which serves as a background of "contextual" data against which program goals and performance measures are formulated and evaluated. Secondly, data from the NHIS serve as the national benchmark against which individual state monitoring efforts are compared.

Under the terms of an interagency agreement, the Bureau of the Census collects the data for the NHIS. The NHIS will be administered using a Computer Assisted Personal Interview (CAPI) system developed by the Bureau of the Census using Blaise

software. A copy of the Federal Register notice announcing the 60-day public comment period is included in Attachment 2.

Privacy Impact Assessment

A Privacy Impact Assessment was submitted on July 13, 2007.

Overview of the Data Collection System

The U.S. Census Bureau is the data collection agent for the National Health Interview Survey. NHIS data are collected by Census interviewers, primarily through personal visits to households. Telephone interviews may be attempted when efforts to make personal contact have not been successful, when the respondent requests a telephone interview, when part of the interview needs to be completed and it is not possible to schedule another personal visit, or when road conditions or travel distances would make it difficult to schedule a personal visit. Nationally, the NHIS uses about 600 interviewers, trained and directed by health survey supervisors in the 12 U.S. Census Bureau Regional Offices. Interviewers (also referred to as Field Representatives) receive training on an annual basis in basic interviewing procedures and in the concepts and procedures unique to the NHIS.

The NHIS is conducted using computer-assisted personal interviewing (CAPI). The CAPI data collection method employs computer software that presents the questionnaire on computer screens to each interviewer. The computer program guides the interviewer through the questionnaire, automatically routing the interviewer to appropriate questions based on answers to previous questions. Interviewers enter survey responses directly into the computer, and the CAPI program determines if the selected response is within an allowable range, checks it for consistency against other data collected during the interview, and saves the responses into a survey data file. This data collection technology reduces the time required for collecting, transferring, processing, and releasing data, and it ensures the accurate flow of the questionnaire. Publically released data sets are available indefinitely on the NCHS internet site.

Responsibility for developing questions and monitoring field work in each of these areas is assigned to NCHS staff. Input to the design of these questions was solicited from experts in a

variety of organizations within the federal government, and from outside researchers and public health professionals.

The Basic Module is repeated every year with little change; this allows for trend analysis and for data from more than one year to be pooled to increase sample size for analytic purposes. The Basic Module contains three major parts: the Family Core (Attachment 3a), the Adult Core (Attachment 3b), and the Child Core (Attachment 3c). The Family Core component collects information on everyone in the family. This allows the NHIS to serve as a sampling frame for additional integrated surveys as needed. Information collected on the Family Core for all family members includes: household composition and sociodemographic characteristics; tracking information; information for matches to administrative data bases; and basic indicators of health status, health behavior, and health care services. The first part of the Family Core serves as the screener questionnaire. Attachment 3 includes the screener component of the Family Core and the OMB statement at the beginning of the computerized instrument.

The Family Core component is administered to any available adult respondent to obtain information about all household and family members. The Adult Core component is administered to a randomly selected adult family member who must respond for him or herself. If there are children in the family, one is randomly selected and the Child Core component is administered to an adult family member who is knowledgeable about that child's health. Finally, recontact information is collected from an adult family member to obtain names, addresses, and telephone numbers of persons who might know their whereabouts if they move.

Items of Information to be Collected

This clearance request is for continuing the Core Module of the NHIS and for Topical Modules each year. In 2010, the modules will be on cancer, occupational injury, epilepsy, an immunization record check follow-up study (continuing from 2009), a split sample study of disability questions (continuing from 2009 with new questions) and child mental health. To put this request in context, a brief description of the overall questionnaire design is given here.

Four broad content domains and associated sub domains are covered by the Core Module: health status, health care services,

health behavior, and sociodemographic characteristics. The sub domains are listed as follows:

Health status

- Conditions
- Injuries/Poisoning
- Activity limitations

Health care services

- Access to care
- Health insurance
- Utilization

Health Behaviors

- Smoking
- Physical Activity
- Alcohol Consumption
- Obesity
- Sleep

Sociodemographics

- Household composition
- Race/national origin
- Education
- Income and assets

The previously approved questions for the Core Module are included in Attachments 3a, 3b, and 3c.

Questions for Topical Modules may be embedded within or attached to one of the principal sections (Family, Sample Adult, and Sample Child). The 2010 Topical Module questions are included in attachments 3d, 3e, 3f, 3g , 3h, 3i, 3j, 3k, 3l, and 3m.

Flashcards used in the administration of the questionnaire are included in Attachment 3n.

In addition to the principal questionnaires, a questionnaire that is used to reinterview a small sample of respondents as a quality control measure is also included (Attachment 3o).

Information in identifiable form (IIF)

Information in identifiable form (IIF) is collected for linkage with other federal sources of data and to enable the MEPS to develop a sampling frame from our data. All of these items have been routinely approved and collected in the past. The identifiable information includes:

- Name
- Date of birth
- Last four digits of the Social Security Number
- Mailing address
- Phone numbers
- Medical information
- Military status
- Employment status

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

There is no web-based data collection. The advance letter states: "You can learn more about the survey at our website: www.cdc.gov/nchs/nhis.htm". There is no content directed at children under 13 years of age.

2. Purpose and Use of Information Collection

The purposes of the NHIS are (1) to provide national data on an annual basis on the incidence of acute illness and accidental injuries, the prevalence of chronic conditions and impairments, the extent of disability, the utilization of health care services, and other health-related topics; (2) to provide more detailed information on selected topics periodically and on a one time basis; and (3) to provide a sampling frame for the Medical Expenditure Panel Survey. It is also a main provider of data for the Congressionally mandated Health U.S. report and provides the majority of indicators used in monitoring progress toward the Healthy People goals.

A major strength of the NHIS is its ability to display health characteristics by selected demographic and socioeconomic characteristics of the U.S. civilian, noninstitutionalized population. The uses of NHIS data are generally in the areas of program planning and evaluation, public health education and health promotion and epidemiological research.

A summary of the need for each of the topic areas of the NHIS Core Module previously approved by OMB follows:

- Conditions

The NHIS is the major source of information on both acute and chronic conditions in the U.S. population. Since risk factors for many chronic diseases are well known and modifiable, information on their prevalence is needed routinely to evaluate the impact of prevention programs. Acute conditions, while often not fatal, have substantial impact on health care utilization and health care costs; information on major acute conditions is needed to appropriately analyze utilization data.

- Injuries

Injuries are a leading cause of disability and premature mortality in the United States. The NHIS has long been a major source of data on the incidence of nonfatal injuries. However, more detailed population-based data on the causes and circumstances of non-fatal injuries, which are vital for designing and evaluating injury prevention programs, have been lacking. The National Committee on Injury Prevention and Control has pointed out the need to build upon and improve existing injury surveillance data collection systems such as the NHIS. To support these needs, the NHIS expanded injury questions in 1997 to increase the level of detail on the circumstances of nonfatal injuries.

- Limitation of Activities

Limitations in physical functioning and in the ability to perform key activities have long been recognized as major health issues and assessment of activity limitation has been done in previous NHIS questionnaires. With an aging and increasingly diverse population, the need to better understand activity limitation is imperative since it is higher among elderly, minority, and economically disadvantaged persons. The 1990 passage of the Americans with Disabilities Act (ADA) also underscored the need for clear and objective data on activity limitation. Finally, functional assessment measures are widely used to determine eligibility for numerous federal assistance programs. NHIS data on functional limitations can help measure the impact of changes in these programs.

- Health Behaviors

As noted above, many of the risk factors for a number of important chronic conditions are related to lifestyle choices (such as smoking and diet). Many of the national health objectives for the Year 2010 are related to health promotion and risk reduction and the NHIS has been identified as the major data source to track progress toward achieving many of these objectives. Most of the items included in this section have been included in previously fielded supplements to the NHIS. Because of their relevance to many national health promotion efforts, a decision was made to incorporate key health behavior items into the NHIS Basic Module.

- Access to Health Care

Recent debate on the U.S. health care delivery system has focused attention on the need for data to assess the types and sources of health care being utilized as well as problems in getting access to needed health care.

- Health Care Utilization

The NHIS Core questionnaire has always included questions on the utilization of hospital and outpatient care services. This information is important to those making decisions about allocation of health care resources and for evaluating the impact of proposed changes in financing of health care services.

- Health Insurance

Since 1990, the NHIS has collected health insurance information on an annual basis. This data is particularly needed by policy analysts to evaluate the impact of any changes.

- Demographic and Socioeconomic Characteristics

As in the past, the NHIS Basic Module will collect information on socioeconomic and demographic characteristics of respondents. One of the well-recognized and longstanding strengths of the NHIS is its ability to allow examination of health measures by a number of demographic and economic variables.

- Recontact and Matching Information

The NHIS continues to collect, on a confidential basis, data needed to recontact respondents for additional information and

to match respondents to administrative records such as the National Death Index. The ability to track respondents and match to other records greatly expands the usefulness of the data at very low cost. Questions related to the use of telephones and cell phones address areas of cell phone usage that are critical for assessment of coverage in telephone surveys.

A summary of the need for each of the 2010 Topical Modules follows:

- Cancer

The supplement is sponsored by the National Cancer Institute (NCI) of the National Institutes of Health (NIH) and the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Coordinating Center for Health Promotion (CCHP), Centers for Disease Control and Prevention (CDC) to assess progress in the prevention and control of cancer in the U.S. population.

Most of the topics in this topical module and many of the questions were used in the 1987, 1992, 2000, and 2005 Cancer supplements to the NHIS. The cancer questionnaires have been used to provide detailed information on cancer epidemiology and control as well as to provide baseline and tracking data on the Year 2020 Health Objectives. The food frequency questions are identical to those in the National Health and Nutrition Examination Survey (NHANES). The NHANES food frequency questions will be analyzed with the NHANES 24-hour dietary recall to develop models to estimate nutrient components from the food frequency. The models can be used to estimate nutrient components in the much larger NHIS sample.

The questions (Attachments 3f and 3g) in this supplement were tested in the NCHS Questionnaire Design Laboratory (QDRL)(OMB No. 0920-0222). Question wording and lead-ins were refined as the result of these tests.

- Occupational Injury

The supplement on Occupational Injury is sponsored by the National Institute of Occupational Safety and Health (NIOSH), CDC. The objective is to obtain data on the prevalence and correlates of work-related health conditions not currently available through traditional occupational health surveillance

systems. The information will be useful to various stakeholders, including the NIOSH National Occupational Research Agenda (NORA) Sector Councils. An occupational health supplement to the NHIS was administered in 1988, but has not been repeated since. The 1988 supplement yielded an important and unique source of surveillance data to measure the magnitude of occupational illnesses and injuries. With the changes in the workplace environment and associated hazards, exposures, and health outcomes that have occurred since 1988, an occupational health supplement to the NHIS is needed.

The occupational health supplement (Attachment 3h) will capture information on workers' longest held jobs. Although information on current or most recent job is collected in the Sample Adult section, information on longest held job is only collected in that section for retired persons. Since many occupational hazards have long latent periods or the effects are greatest with cumulative exposure, it is important to know about a person's longest held job.

Information is sought on employment arrangements and work schedules because precarious employment arrangements and shift work have been reported in the literature to have an impact on occupational illness and injury. Information about key hazardous occupational physical/chemical and psychosocial exposures is not currently available elsewhere at a national level.

Because the NHIS is a household survey, the supplement provides a perspective that BLS's Survey of Occupational Injuries and Illnesses (SOII) does not. The SOII is an employer-based survey that measures incidence while NHIS measures prevalence of the specific work-related conditions in the population¹. According to a BLS collaborator, the NHIS supplement "better assesses the burden of the work-related conditions on society at the time of the survey, while the SOII is better suited to tracking where these conditions are currently arising." In addition, the NHIS supplement includes persons who are self employed and those who have physician diagnosed conditions but who have not missed work or changed work responsibilities, two areas of undercoverage cited in a recent GAO analysis of the SOII². The GAO report also emphasizes the importance of interviewing workers to obtain a more complete picture of workplace injury and illness.

Estimates based on SOII and NHIS data will differ. As an incidence survey that does not cover the entire range of employers, SOII is likely to produce lower estimates than the

NHIS of occupational illnesses and injuries. NHIS results can be examined for recent diagnoses and for the same types of employers included in the SOII to allow comparisons between the two surveys.

¹ Ruser, JW. *Examining Evidence on Whether BLS Undercounts Workplace Injuries and Illnesses*. Monthly Labor Review. August 2008.

² Workplace Safety and Health: *Enhancing OSHA's Records Audit Process Could Improve the Accuracy of Worker Injury and Illness Data*. [GAO-10-10](#), October 15, 2009.

- Epilepsy

The 2010 NHIS includes three questions related to epilepsy on the Sample Adult questionnaire. The single item NHIS question on epilepsy is a useful indicator of possible seizure disorder: ("Have you ever had epilepsy or seizures?"), but alone is insufficient to document doctor-diagnosed epilepsy. Additionally, it conflates seizures associated with non-epilepsy related causes with seizures known to be caused by epilepsy. The distinction is important, as epilepsy indicates the need for ongoing treatment, and often, specialty care. The inclusion of the proposed follow-up questions (Attachment 3i) will provide for the opportunity to assess doctor-diagnosed epilepsy; identification of current treatment and symptoms associated with epilepsy (i.e., classification of active cases of epilepsy); access to specialty care for epilepsy; and assess the impact of epilepsy and its treatment on quality of life.

These questions, along with the standard NHIS questions that ask about behavioral risk factors and comorbid conditions will allow us to assess the health status of adults with epilepsy, their comorbidity, and risk factors compared to the general population. The inclusion of the existing NHIS questions along with the proposed questions can also provide more distinctions between incidence and prevalence of epilepsy. These data can inform the development of prevention programs targeting adults with epilepsy who are at increased risk for poor health outcomes not only due to their seizure disorder, but also because of risky lifestyle behaviors associated with other chronic diseases.

- Immunization

This section includes two components: an immunization record check study and questions to capture immunizations using the pandemic flu vaccine.

The module on immunization record checks appeared in the 2001 NHIS and began again during 2009. Vaccines are important defenses against infectious diseases, and prevent major causes of illness, disability, and death. This module will compare information about immunizations from respondents to immunization records maintained by health care providers. For this module, respondents will be asked for permission to obtain immunization records from their child's (or children's) immunization provider(s). Because provider records are more complete than household records, immunization history records are then obtained from providers to determine up-to-date status of children. This module applies to children 19 through 35 months of age and 13 through 17 years of age, the same as the National Immunization Survey-Child and Teen components. Medical providers will then be contacted to provide information on Child Immunization History or Teen Immunization History. Questions embedded in the NHIS to capture provider information are included in Attachment 3d. Questions to be asked of health care providers are included in attachments 3l and 3m.

The pandemic flu outbreak has led to the development of vaccines to address this virus. This year both the traditional seasonal flu vaccine and the pandemic flu vaccine will be available. Questions in Attachment 3d include questions to capture information about immunization for both types of vaccines.

- Disability Split Sample Study

The topical module on disability and secondary conditions is a test of methods that will replicate approaches used to assess disability on the American Community Survey (ACS)(OMB No. 0607-0810) and a recommended set of questions from the Washington Group on Disability Statistics, which was formed as a result of the United Nations International Seminar on Measurement of Disability. A split-ballot approach in the NHIS will randomly assign each family to either the ACS or the Washington Group approach. The primary goal is to identify whether there is an impact on estimates of disability reporting due to the two different sets of questions. Questions are in Attachments 3e and 3k).

- Child Mental Health

Section 520 [42 USC 290bb-31] of the Public Health Service Act, establishes the Center for Mental Health Services (CMHS), Substance Abuse and Mental Health Services Administration (SAMHSA), and authorizes the Center to conduct surveys with respect to mental health. To monitor the prevalence children and youth with mental health problems, SAMHSA and the National Institute of Mental Health (NIMH), through a reimbursable agreement with the NCHS have funded questions on children's mental health on the NHIS. Questions (Attachment 3j) include the short Strengths and Difficulties Questionnaire and a series of questions on mental health services.

Privacy Impact Assessment Information

A Privacy Impact Assessment was submitted on July 13, 2007. The NHIS continues to collect, on a confidential basis, data needed to recontact respondents for additional information and for participation in the Medical Expenditure Panel Survey and to match respondents to administrative records such as the National Death Index. The ability to track respondents and match to other records greatly expands the usefulness of the data at very low cost.

Only those NCHS employees, specially designated agents, including the U.S. Census Bureau, and our full research partners who must use the personal information for a specific purpose can use such data. Everyone else who uses NHIS data can do so only after all identifiable information is removed.

The collection of information in identifiable form requires strong measures to ensure that private information is not disclosed in a breach of confidentiality. All NCHS employees as well as all contract staff receive appropriate training and sign a "Nondisclosure Statement." Staffs of collaborating agencies are also required to sign this statement and outside agencies are required to enter into a more formal agreement with NCHS. The transmission and storage of confidential data are protected through procedures such as encryption and carefully restricted access. See A10 for more details.

3. Use of Improved Information Technology and Burden Reduction

The survey will be conducted by Computer Assisted Personal Interview (CAPI), using Blaise software, which reduces the time required for collecting, transferring data, processing data, and releasing data. CAPI usually reduces the average duration of interviews, compared to a paper questionnaire with identical content.

4. Efforts to Identify Duplication and Use of Similar Information

During the course of development of the redesigned NHIS, numerous individuals were consulted, both formally and informally. The names and organizations of the most directly involved individuals are cited in Attachment 4a. Consultation included not only issues of design and content but also knowledge of existing surveys or data. In addition, a search was made of the literature to ascertain the uniqueness of the items.

The end-users consulted are primarily from the agencies and offices in the Federal government which use NHIS data for policy planning and evaluation, such as Dale Hitchcock, Director, Division of Data Policy, Office of Science and Data Policy, Office of the Assistant Secretary Planning and Evaluation, DHHS.

Consultation took place in face-to-face meetings, telephone conferences, electronic mail, and postal mail, and there were multiple contacts with many of the individual consultants.

Consultations were also held for the 2010 Topical Modules (Attachment 4b).

The Board of Scientific Counselors (BSC) of the National Center for Health Statistics (NCHS) commissioned a panel to review the NHIS. The panel members are identified in Attachment 4c. The panel issued a report on 21 November 2008, which is included in Attachment 4d.

Other surveys were reviewed to determine possible duplication. Because the NHIS is the principle health survey conducted by the Department of Health and Human Services, the Basic Module items are not duplicated in their entirety in any other national data system. In fact other surveys borrow questions from the NHIS for

new surveys. To the extent that there is some overlap in content of the Basic Module with other surveys, it is because it is necessary to insure that the full range of relevant variables are included for complex analyses of data on the NHIS sample.

The Survey of Occupational Illnesses and Injuries conducted by the Bureau of Labor Statistics produces estimates on new cases of employer reported illnesses and injuries. The NHIS approach will produce population-based prevalence rates that will provide more information on the overall impact of occupational illnesses and injuries.

5. Impact on Small Businesses or Other Small Entities

Information collection for the NHIS does not involve small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

The continuous nature of the NHIS is necessary for several reasons. First, many of the data items collected in the NHIS are used for annual tracking of health events and circumstances, including tracking of the National Objectives for Health Promotion and Disease Prevention and the prevalence of HIV/AIDS testing. Second, the continuous design makes it possible to aggregate data over longer periods of time to include enough cases to study rare events and small populations, such as minority groups. Third, the Medical Expenditures Panel Surveys (Household Component and Medical Providers Component, OMB No. 0935-0118) now depends on the NHIS for their sample, and failure of the NHIS to collect data annually may cause this survey to be postponed or canceled. Fourth, a continuous survey is more cost effective because it makes possible a stable interviewing staff, which increases the quality of the data and avoids start-up and shut down costs. Reducing the frequency of data collection would undermine all of these desirable features of the NHIS.

Respondents are asked to respond to the NHIS only one time.

There are no legal obstacles to reducing the burden.

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

This request fully complies with the regulations 5CFR 1320.5.

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

A. Public Comment

In compliance with 5 CFR 1320.8(d), an agency 60-day notice soliciting comments on this data collection was published in the Federal Register on May 28, 2009 (Vol. 74, No. 101, pages 25553-25554) (Attachment 2). Comments were received from the Asian & Pacific Islander American Health Forum (APIAHF). The incoming letter and the program's response are in Attachment 5c.

B. Other consultations outside the agency

Major consultations took place in 1995 and 1996 when the Basic Module content was being developed. In summary, the consultation was very broad and included survey design experts, experts on the substantive health topics covered in the questionnaires, and end users of the data (Attachment 4a).

The survey design experts included several paid consultants who reviewed draft documents and attended monthly redesign staff meetings; they were Thomas Jabine, a Washington DC consultant; James Lepkowski of the University of Michigan; and Floyd Fowler of the University of Massachusetts.

The substantive experts included many scientists on the staffs of NIH and CDC, and university-based researchers; to name just a few of those who reviewed documents and provided written comments: Barbara Starfield of the Johns Hopkins University; Paul Newacheck of the University of California, San Francisco; and Thomas Achenbach of the University of Vermont.

The end-users consulted are primarily from the agencies and offices in the Federal government which use NHIS data for policy planning and evaluation, such as Dale Hitchcock, Director, Division of Data Policy, Office of Science and Data Policy, Office of the Assistant Secretary Planning and Evaluation, DHHS. Consultation took place in face-to-face meetings, telephone conferences, electronic mail, and postal mail, and there were multiple contacts with many of the individual consultants. While not all recommendations by consultants could be accommodated, the content of Basic Module of the NHIS questionnaire was almost entirely selected on the advice of

outside consultants. No major problems remained unresolved following the consultations.

Consultations were also held for the 2010 Topical Modules (Attachment 4b)

The Board of Scientific Counselors (BSC) of the National Center for Health Statistics (NCHS) commissioned a panel to review the NHIS. The panel members are identified in Attachment 4c. The panel issued a report on 21 November 2008, which is included in Attachment 4d. The report states, "The NHIS is the gold standard for U.S. survey data. The size, scope and the quality of the NHIS data set it apart from the vast majority of other U.S. health surveys."

9. Explanation of Any Payments or Gifts to Respondents

N/A. No payments will be made to respondents in the NHIS.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality provided to respondents is assured by adherence to Section 308(d) of the Public Health Service Act (42 USC 242m) as follows (Attachment 5a):

All information which would permit identification of an individual, a practice, or an establishment will be held confidential, will be used for statistical purposes only by NCHS staff, contractors, and agents only when required and with necessary controls, and will not be disclosed or released to other persons without the consent of the individual or the establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347).

In addition, legislation covering confidentiality is provided according to section 513 of the Confidential Information Protection and Statistical Efficiency Act (PL 107-347) which states:

"Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by section 512, comes into possession of such information by

reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this title, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than 5 years, or fined not more than \$250,000, or both."

Privacy Impact Assessment Information

The NCHS Privacy Act Coordinator has reviewed this request and has determined that the Privacy Act is applicable. The Privacy Act System of Records name is 09-20-0164 Health and Demographic Surveys Conducted in Probability Samples of the U.S. Population.

Data will be treated in a confidential manner. The process of informing respondents of the procedures used to keep information confidential begins with material mailed in advance (Attachment 5b), and will carry through to interviewer training and all communications with potential respondents. Materials will include all elements of informed consent, including the purpose of the data collection, the voluntary nature of the survey, with whom the information will be shared, and the effect upon the respondent for not participating.

To further aid interviewers in guarding the confidentiality and security of data, all data collected in this project will be collected on laptops that are secured with encryption software. This software encrypts data contained on the computer, and has two levels of password protection. In the event of computer theft or other loss of the computer, the software prevents unauthorized access to any data on the computer, thereby adding an extra layer of security and confidentiality to the data.

In this survey, as in others, NHIS will include a routine set of measures to safeguard confidentiality, including the following: all staff who have access to confidential information are given instruction by NCHS staff on the requirement to protect confidentiality, and are required to sign a pledge to maintain confidentiality; only such authorized personnel are allowed access to confidential records, and only when their work requires it; when confidential materials are moved between locations, records are maintained to insure that there is no loss in transit; and when confidential information is not in use, it is stored in secure conditions.

It is NCHS policy to make NHIS data available via public use data files to the scientific community. Confidential data will never be released to the public. For example, all personal identifiers are removed from the public release files; this includes participant name, address, survey location number, sample person number, and so forth. A concerted effort is made to avoid any disclosures that may allow a researcher to go back and find individuals in the general population. All data releases are reviewed by the NCHS Disclosure Review Board to avoid data breaches, such as release of detailed geographic information that may allow anyone to identify practices or individuals in the general population.

The survey was approved by the Institutional Review Board (the NCHS Research Ethics Review Board) on 23 June, 2009 (Attachment 5d).

11. Justification for Sensitive Questions

Some of the NHIS research topics include potentially sensitive questions. In the informed consent procedure, all sample persons are advised of the voluntary nature of their participation in the survey or any of its components. Sample persons are informed that they can choose not to answer any individual questions and may stop the interview at any time.

All questions and procedures are reviewed by the NCHS Research Ethics Review Board for issues of sensitivity (Attachment 5d). The potential sensitivity of questions was an evaluation criterion in determining content of the survey. The multipurpose nature of the NHIS makes it necessary to exclude topics so sensitive that they may interfere with participation.

Questions asked about the following are thought to be of a sensitive nature:

- Social Security and Health Insurance Claim Number (last four digits)
- Citizenship Status
- Intentional Injuries
- Street Living
- Sexually Transmitted Diseases

Social Security Number and Health Insurance Claim Number

The last four digits of the Social Security Number(SSN)is asked on the NHIS questionnaire to allow linkage with administrative and vital records in the Department, such as the National Death Index (NDI). The NDI is a computerized central file of death record information. It is compiled from tapes obtained by NCHS from the State vital statistics offices. The tapes contain a standard set of identifying information on decedents from 1979 to the present. Records are matched using Social Security Number and other variables such as name, father's surname, date of birth, sex, state of residence, and marital status. Of these, Social Security Number is the most important identifier for successful matching. The last four digits has been shown to be nearly as effective for matching as the full number.

The Social Security Number is also used by the Medical Expenditure Panel Study to help track the location of respondents who have changed residence since their NHIS interview. Finding a correct address for respondents is essential to maintaining response levels at an acceptable level in linked surveys, and the Social Security Number is a key item for establishing a correct address.

Medicare beneficiaries are given a health insurance claim (HIC)number that is their (or their spouse's) SSN with an alphabetic prefix. The NHIS also asks for the last four digits of that number so that the NHIS data can be linked to Medicare claims information for purposes of statistical research.

Before the questions on SSN and HIC are asked, respondents are informed of their purpose and given an assurance of confidentiality:

Finally, we would like the last four digits of your Social Security Number and the last four numbers and any letters of your Medicare number. This information will help us link your survey data with health-related records of other government agencies, and allow us to conduct additional research without taking up your time with more questions. The National Center for Health Statistics uses this information for research purposes only. Providing this information is voluntary. Federal laws authorize us to ask for this information and require us to keep it strictly private. There will be no effect on your benefits if you do not provide this information.

* Read if necessary: The specific federal laws are the Public Health Service Act (Title 42, United States Code, Section 242K) and the Confidential Information Protection and Statistical Efficiency Act (Title V of Public Law 107-347).

If the respondent asks for more information about the purpose and confidentiality of these questions, the interviewer can display a standard help screen on her computer and read it to the respondent.

Citizenship Status

Because recent changes in welfare legislation affect the health care coverage of some U.S. residents who are not citizens, it is now more important to obtain information about the citizenship status of NHIS sample persons. For that reason, since 1998 the NHIS asked the following question about all members of sample families as part of the Family Core: {Are/Is} {you/subject name} a CITIZEN of the United States?

The respondent will be asked to select a response from this printed list:

- (1) Yes, born in the United States
- (2) Yes, born in Puerto Rico, Guam, American Virgin Islands, or other U.S. territory
- (3) Yes, born abroad to American parent(s)
- (4) Yes, U.S. citizen by naturalization
- (5) No, not a citizen of the United States

If necessary, the Field Representative will read the following statement:

Information about citizenship is being collected by the Department of Health and Human Services to perform health-related research pertaining to place of birth and length of time in the United States. Providing this information is voluntary and is collected under the authority of the Public Health Service Act. There will be no effect on pending immigration or citizenship petitions.

Intentional Injuries

The questions on injuries and poisoning are intended to elicit a full account of the circumstance surrounding such events, including whether or not they were intentionally caused by another person. Although no direct questions are asked about intentionality or the identity of other persons, it is possible that respondents would report incidents of child abuse to an interviewer. Legal counsel advised NCHS that if that were to occur, Federal law protecting the confidentiality of the interview would take precedence over a State law requiring that evidence of child abuse be reported to authorities.

Furthermore, by analyzing previously collected NHIS data, it was determined that reports of child abuse are extremely rare in NHIS interviews, and that when they occur they almost always refer to events many years past. For those reasons, NCHS decided that it is not necessary to inform respondents in advance that the questions about injury and poisoning could lead to disclosure of child abuse. The NHIS Research Ethics Review Board reviewed and concurred in that decision.

Street Living

The following question will be asked of the sample adult. It covers three risk factors for tuberculosis transmission and control. It is patterned after a similar question in the AIDS section.

Have you ever spent more than 24 hours living on the streets, in a shelter, or in a jail or prison?
(1) Yes
(2) No

Sexually Transmitted Diseases

It is critical to clarify risk factors and identify at-risk population subgroups associated with sexually transmitted diseases to plan and evaluate prevention efforts.

Selected questions are asked of the sample adult and focus on testing for HIV status. These questions, unchanged from the last approval, are included in Attachment 5a.

12. Estimates of Annualized Burden Hours and Costs

A. Time Estimates

This submission requests OMB approval for three years of data collection beginning with the 2010 NHIS. These data collections will occur within the context of ongoing data collection activities (OMB 0920-0214). The burden for each survey component of one complete survey cycle is shown in the table below.

As shown below, the estimated total burden for the 2010 survey, including the screening and reinterview components is 36,544 hours.

The screening component involves asking a short set of questions contained in the NHIS Coverage (COV) and Household (HHC) components of the Core NHIS used to determine whether the household includes a black, Hispanic or Asian person (More detail on the screening component is contained below in section B.1). Approximately 10,625 of the screener designated households are not selected into the full NHIS survey. These households spend about 5 minutes to complete the screening components. The total burden for screener households who are not selected into the full survey is about 885 hours.

Lines 2-11 describe the various sections of the core and topical modules. Finally, a small quality control resurvey of about 3,188 participating households is conducted.

Average Annual Burden

Questionnaire (respondent)	Number of respondents	Number of Responses per Respondent	Average burden per respondent in hours	Total burden In hours
Screener Questionnaire	10,625	1	5/60	885
Family Core (adult family member)	35,000	1	23/60	13,417
Adult Core (sample adult)	26,500	1	17/60	7,508
Child Core (adult family member)	10,625	1	9/60	1,594
Child and Adult Immunization (adult family member)	10,000	1	4/60	667

Family Disability (adult family member)	17,500	1	3/60	875
Adult Cancer (sample adult)	26,500	1	19/60	8,392
Child Cancer (adult family member)	10,625	1	1/60	177
Adult Occupational Injury (sample adult)	26,500	1	2/60	883
Adult Epilepsy (sample adult)	26,500	1	1/60	442
Adult Quality of Life (sample adult)	6,641	1	5/60	553
Child Record Check (medical provider)	1,275	1	5/60	106
Teen Record Check (medical provider)	5,100	1	5/60	425
Child Mental Health (adult family member)	10,625	1	2/60	354
Reinterview Survey	3,188	1	5/60	266
Total				36,544

Not all questions apply to each person, and the questionnaire instrument automatically skips over questions that do not apply, based on earlier information given by the respondent. Thus, no respondent is ever asked all of the questions in the questionnaire.

The estimate of response burden above is based on an average length of interview per household. Variations occur in individual household interview times primarily because of differing numbers of

persons in the household and variations in the number of health conditions reported in the household.

The burden on any single member of a sample family also varies according to who is designated respondent for each module. In some sample families the same adult could be the respondent for all of the major components: Family, Adult, and Child; in other families there could be a different respondent for each of the Basic Modules. In the first case, the total average burden on the single respondent would be about one hour; in all other cases the burden on a single respondent would be less.

B. Cost to Respondents

At an average wage rate of \$20.00 per hour and an average length of interview of about 9.65 minutes for the 227,204 respondents (including those who screen out of the survey), the average cost per respondent is about \$3.22. (Wage rate information is from the Bureau of Labor Statistics:<http://www.bls.gov/ncs/ocs/sp/nctb0298.pdf>). This estimated cost does not represent an out of pocket expense, but represents a monetary value attributed to the time spent doing the interview.

Total Burden Hours	Respondent Wage Rate per Hour	Total estimated costs
36,544	\$20.00	\$730,880

13. Estimates of Other Total Annual Cost Burden to Respondents or Record keepers

None.

14. Annualized Cost to the Government

As shown in the table below, the total cost of the 2010 NHIS is estimated to be about \$31 million, which includes costs to NCHS directly and to its fieldwork contractor, the Bureau of the Census. For NCHS, the estimated cost for the 2010 data collection is about \$7 million. This cost includes work on survey design, evaluation, analysis, comparability studies, coding, processing, questionnaire design laboratory testing, field pretests, weighting, and estimation, printing of survey materials, and staff observation costs (travel and per diem). It is estimated that Census Bureau costs for survey planning, design, and data collection for the 2010

NHIS will be about \$24 million, which is transferred to the Census Bureau through an Interagency Agreement.

Total 2010 Survey Costs	31 million
U.S. Bureau of the Census (Interagency Agreement)	24 million
Sampling	3.5 million
Survey Management	1.0 million
Field Operations	17.0 million
Data Editing	1.0 million
Programming and IT	1.5 million
National Center for Health Statistics	7 million

Approximately \$8 million of these costs are provided to NCHS through Interagency Agreements with survey sponsors.

15. Explanation for Program Changes or Adjustments

The current NHIS burden is 28,017 hours. For the 2010 NHIS survey the total burden is estimated to be about 36,544 hours, an increase of 8,527 hours. The total burden is higher because the supplements are longer in 2010 and the sample size reflects a full 16-panel sample plus an extra panel during the first quarter.

16. Plans for Tabulation and Publication and Project Time Schedule

The following are key activities and projected completion dates for the 2010 NHIS:

<u>Activity</u>	<u>Projected Completion Date</u>
o Interviewer training	January 2010
o 2010 data collection	January - December 2010
o Early release of selected estimates (quarter 1)	September 2010
o 2010 data tape available	June 2011
o Publication of summary statistics	January - March 2012

17. Reason(s) Display of OMB Expiration Date is Inappropriate

N/A. Not requesting exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.