

Supporting Statement A

Revision Request for Clearance

NATIONAL HEALTH INTERVIEW SURVEY

OMB No. 0920-0214, Expiration Date 12/31/2017

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Supporting Statement

NCHS National Health Interview Survey

- Goal: to collect data to measure and monitor the amount, distribution, effects, and risk of illness and disability in the population and the utilization of health care services for such conditions and barriers to utilization.

- Intended use: For use by the Department of Health and Human Services (DHHS) and the public to monitor trends in illness and disability and to track progress toward achieving many of the Healthy People objectives for the nation, and for the public health research community to conduct epidemiologic and policy analysis of such timely issues as characterizing those with various health problems, determining barriers to accessing and using health care, and evaluating the impact of changes in federal health programs.

- Data collection methods: annual, in-person household interviews of civilian, non-institutionalized persons residing in the United States via Computer Assisted Personal Interview with telephone follow-up when needed, supplemental interviews may use Computer Assisted Telephone Interviewing.

- Subpopulation to be studied: Civilian noninstitutionalized population residing in the United States

- Data analysis methods: descriptive, bivariate, and multivariate statistics, including frequencies; chi-square and t-tests; and linear, logistic, and multilevel regression.

This revision request is to modify selected sections of the National Health Interview Survey (NHIS) (OMB# 0920-0214, expires 12/31/2017) to add annual and periodic questions; to delete annual and periodic questions; to test the feasibility of using nonprobability samples (e.g., web panels); to conduct methodological projects (e.g., split-ballot experiments); to survey subsamples of former or current NHIS respondents; and to change the sources from which the sample is drawn. The NHIS is a critical ongoing information source on the health of the civilian, noninstitutionalized population of the United States. A three year clearance is requested.

In this application, we seek OMB approval to:

- Conduct the National Health Interview Survey in 2016 to 2018.
- Continue the increase in the previous three years' sample size.
- Carry out probability and nonprobability methodological testing that will inform the 2018 questionnaire redesign, using either a split-ballot or a follow-back design or both (as noted in Line 5 of the burden table).
- Modify selected sections of the 2016 to 2018 questionnaires. For example, the 2016 NHIS will include supplementary questions on diabetes risk factors, ABCS of heart disease and

stroke prevention, immunizations, hepatitis B and C screening, blood donation, the impact of the Affordable Care Act, family food security, child mental health, functioning and disability, vision, chronic pain, balance, use of non-cigarette tobacco products and e-cigarettes, inflammatory bowel disease, and internet and email usage—most of which appeared on the NHIS in previous years. The 2017 survey will include the same or similar supplementary questions, as well as questions to track progress toward achieving the objectives set forth in Healthy People 2020.

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 issues as characterizing those with various health problems, determining barriers to accessing and using 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) (OMB# 0935-0118). This survey is conducted by the Agency for Healthcare Research and Quality. MEPS uses completed interviews from the NHIS to identify and select the desired sample, contact that sample to collect additional data, and combine their survey data with the original NHIS data. These procedures reduce survey costs, reduce overall burden on the public, and increase the amount of data available for critical health-related analysis.

The NHIS has been conducted every year since 1957. The current design of the NHIS questionnaire was implemented in 1997, and consists of a standard basic or Core Module, covering general health topics and demographic characteristics that is repeated every year. In addition to the Core Module, each year supplementary questions or modules are included. For example, the 2016 NHIS will include supplementary questions on diabetes risk factors, ABCS--aspirin, blood pressure, cholesterol, smoking--of heart disease and stroke prevention, immunizations, hepatitis B and C screening, blood donation, the impact of the Affordable Care Act, family food security, child mental health, functioning and disability, vision, chronic pain, balance, use of non-cigarette tobacco products and e-cigarettes, inflammatory bowel disease, and internet and email usage. 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 care 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 and other national surveys are compared.

Results from Recent Projects to Enhance the Utility of the NHIS and Implications for anticipated Projects for 2016 -2018

Supplements: In addition to a core set of data that is collected each year and remains largely unchanged for years at a time, sponsored supplements vary from year to year. For 2016, supplemental questions will be cycled in pertaining to diabetes risk factors, balance, blood donation, vision, and chronic pain. Supplemental topics that will continue in 2016 largely unchanged from previous years (many most recently from 2015) are related to the Affordable Care Act, ABCS of heart disease and stroke prevention, inflammatory bowel disease, hepatitis B and C screening, child mental health, family food security, disability and functioning, non-cigarette tobacco and e-cigarettes, immunizations, and sexual orientation. The core set of questions remains unchanged from 2015 and includes socio-demographic characteristics, health status, health care service use, health care coverage, health conditions, and health behaviors.

Follow-back survey and other special projects: In 2013 and 2015, NCHS conducted follow-back surveys with prior NHIS respondents to expand the depth and breadth of information related to the Affordable Care Act, to monitor changes in health care coverage, and to examine the impact on health care coverage-related estimates of different modes of data collection and location of the questions within the survey. The **2013** follow-back survey, the National Health Care Interview Survey (NHCIS), included questions on financial burden of health care, health status, health care access and use, health insurance, use of preventive services, health care satisfaction, family food security, and smoking, and examined response rates for web and telephone implementation. Based on results from the NHCIS, which showed a 22% web completion rate, it was determined that creating a web panel from previous NHIS respondents was not feasible. Web implementation captured a younger and more educated group than was reached by phone. Generally, however, combining web and telephone modes increased the overall response rate. Other embedded experiments examined the mode of initial contact—mail, web, telephone—and the impact of a monetary incentive on response rates. Whereas mode of notification was not found to impact response rates, offering a monetary incentive of \$10 nearly doubled response rates among web completers, and a \$20 incentive increased them 2.5-fold. By contrast, the incentive did not show an impact on response rates among telephone completers. Finally, among those who answered by

web, this was the preferred mode for future surveys, whereas telephone respondents favored telephone and mailed questionnaires.

The second follow-back survey carried out in **2015**, the National Health Care Coverage Survey (NHCCS), began field work in September 2015. Its aims are (1) to ascertain the quality of information that can be derived from a shorter battery of questions on health insurance coverage compared to the questions currently in use on the NHIS, and (2) to compare responses obtained from different adult family members about the family's health insurance coverage. Both these aspects will be used to inform decisions for the 2018 questionnaire redesign.

For **2016 and 2017**, similar special projects will build on and extend the findings from the previous two follow-back surveys and will be used to inform the impending questionnaire redesign. Activities may include pilot testing new and/or updated questionnaire items, shortened topical areas, and comparing quality of information collected from different adult respondents in the household. These activities may be carried out using a follow-back design similar to that used for the 2013 and 2015 follow-back surveys, or nonprobability web panels of prior NHIS respondents or commercially obtained. In addition, pending funding, another special project is intended to test the use of wearable devices as a source of enhanced biometric health data, which would be embedded in the regular NHIS interview.

The test of incentives to improve response rates that was carried out in **2015** will not continue in 2016. The 2015 experiment was conducted in the states included in three Census Regional Offices: New York, Philadelphia, and Denver. The experimental design involved two components: a \$5 cash unconditional advance token incentive mailed to families with the introductory letter, and a \$20 incentive (in the form of a debit card) for completion of both the Family and the Sample Adult component of the NHIS interview. Families were randomly assigned into each of the two components, and the resulting comparison groups were \$0, \$5, \$40, and \$45. Preliminary results indicate that overall, using incentives improved response rates as much as 4 percentage points among some groups, whereas in other groups there was no improvement. Analysis of the data is underway but the initial conclusion is not to give incentives across the board. For **2016-2018** we may conduct small studies which may thus employ targeted applications of incentives when they are deemed to be beneficial to the study design; the test of using wearable devices is one example of such an application.

Sample expansion: High quality state-level data are critical to monitor the impact of the Affordable Care Act. The NHIS base sample has been used to produce estimates on key health care coverage information for the nation for 20 to 30 states. There is keen interest in expanding the number of states for which the NHIS can provide annual estimates. Additional funding has been provided to NCHS for sample expansion in **2016**, enabling estimates for many health indicators including health insurance coverage to be produced for most states. It is also possible to pool 2 or more years of data to examine smaller population groups or rarer event data.

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 and other follow-back surveys. It is also a main provider of data for the Congressionally-mandated *Health, United States* report and provides data for many indicators used in monitoring progress toward the Healthy People goals and for detailing health disparities.

A major strength of the NHIS is its ability to display health characteristics by selected demographic and socio-economic 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. .

- 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 2020 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, key health behavior items are incorporated into the NHIS Core Module.

- Access to Health Care

Recent changes to the U.S. health care delivery system have focused attention on the need for data to assess the types and sources of health care being utilized as well as barriers to obtaining 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 extensive health insurance information on an annual basis. These data are particularly needed by policy analysts to evaluate the impact of changes to health care delivery and financing.

- Demographic and Socio-economic Characteristics

As in the past, the NHIS Core Module will collect information on socio-economic and demographic characteristics of survey subjects. 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 and mitigates public burden. Collecting data on computer usage and respondents' email addresses provides insight into the best means for recontact.

- Supplementary Questions

A summary of the 2016 supplementary questions follows, and is summarized in table form in Attachment 3.

New Supplements

Balance: Sponsored by the National Institute on Deafness and Other Communication Disorders (NIDCD, NIH), these questions are repeated in reduced form from a similar battery that was included on the 2008 NHIS (for adults) and the 2012 NHIS (for children). The questions address the programmatic need for data on the impact of dizziness and balance on the health and well-being of adults and children as part of the Healthy People 2020 initiative.

Blood Donation: Sponsored by the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP, CDC), this single question is similar to the question included on the 1997-2010 NHIS and is on the survey to gather data for the Healthy People 2020 initiative.

Chronic Pain: Sponsored by the National Institute on Neurological Disorders and Stroke (NINDS) and the National Center For Chronic Disease Prevention and Health Promotion (NCCDPHP, CDC), this set of questions are on the NHIS to establish the prevalence of chronic pain and impact on daily life for adults.

Diabetes: Sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK, NIH) and the National Center For Chronic Disease Prevention and Health Promotion (NCCDPHP, CDC), this set of questions was newly-developed and underwent extensive cognitive testing to ask adult respondents about their risk factors for diabetes, about medication use for those with diabetes, gestational diabetes, and use of diabetes prevention programs.

Vision: Sponsored by the National Eye Institute (NEI, NIH), this battery of questions last on the NHIS in 2008 asks questions for adults and children about conditions of the eye, visual acuity, and use of protective eye wear. These questions measure Healthy People 2020 objectives.

Continuing Supplements

Impact of the Affordable Care Act: A number of questions on access and utilization of health care were added in 2011 to the Family, Sample Adult and Sample Child Modules. These included questions on expansion of health care coverage for young adults, access to health care providers, health information technology use, and direct purchase of health insurance. In October 2013, a few questions were added about income-based health insurance premiums for private plans (in the Family Module) and whether the respondent had looked into purchasing health insurance through the Health Insurance Marketplace (in the Sample Adult Module). A few additional premium-related questions similar to those added in October 2013 were added in 2014 for Medicaid, state-sponsored health plans, and other government health plans, located in the Family Module. For the 2015 NHIS, approximately 25 supplemental ACA questions were dropped from the survey, due to funding constraints. For 2016, the 2015 version of the health care coverage questions continues.

Heart Disease and Stroke: Beginning in 2012 and continuing for 2016, four questions on aspirin use have been embedded in the Sample Adult Conditions Sections (ACN) to address the CDC ABCS initiative to focus on appropriate aspirin therapy (the “A” in ABCS). These were joined in 2015 with items on medication use for high blood pressure and cholesterol. The same battery of questions continues for 2016.

Family Food Security: A ten question set of items on food security sponsored by the United States Department of Agriculture (USDA) continues for 2016. These questions assess whether the family has been able to afford adequate food for all adults during the previous 30 days.

Child Mental Health: Six items to measure mental strengths and difficulties for children age 4-17 continue in 2016. These items have been on the NHIS in some form since 2001.

Non-cigarette Tobacco and E-Cigarettes: Questions pertaining to use of non-cigarette tobacco products and e-cigarettes are retained from the discontinued 2015 NHIS Cancer Control Module. They are located in the Adult Behaviors core module. Developed in collaboration with the Food and Drug Administration (FDA), the Office of Smoking and Health (CDC), and the National Cancer Institute (NIH), the supplemental questions measure the prevalence and frequency of using non-cigarette tobacco products such as cigars, pipes, and smokeless tobacco as well as e-cigarettes.

Inflammatory Bowel Disease: Continuing in 2016 is one question that was added in 2015 to determine the prevalence of inflammatory bowel disease (specifically Crohn’s Disease or ulcerative colitis). This question is sponsored by CDC’s National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), and prior to 2015 was last on the NHIS in 1999.

Immunization: A set of questions to measure vaccination coverage for hepatitis, tetanus, shingles (adults), and influenza immunizations for Sample Adults and Children continue for 2016. They are sponsored by the National Center for Immunization and Respiratory Diseases (NCIRD, CDC).

Hepatitis B and C Screening: Funded by CDC’s National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), these supplemental questions have been on the NHIS since 2013 and

continue in 2016. They ask about the receipt of screening for hepatitis B and C, and the reasons for having been screened for hepatitis C.

Functioning and Disability: Two sets of disability items continue for 2016. The first set is a six-item series that closely approximates the disability questions that appear on the American Community Survey (ACS). As part of a larger test of these questions, comparisons of responses will be made between the NHIS and the ACS. The items cover difficulty hearing, seeing, recall, mobility, dressing/bathing, and doing errands. The second set was developed by the United Nations Washington Group on Disability Statistics. The questions are asked in national health surveys in multiple countries in order to better understand and compare functional limitations across many cultures. These data will allow us to compare levels of social participation (for example, employment, education or family life) between persons with disabilities and persons without disabilities.

Additions to Core NHIS

English Proficiency: As required by Section 4302 of the Affordable Care Act (see Attachment 1), a question that addresses English proficiency was added to the Core NHIS in 2013. This item continues for 2016:

Question Text:

How well {fill: do you/does NAME} speak English? Would you say...

*Read categories below.

- 1 Very well
- 2 Well
- 3 Not well
- 4 Not at all
- 7 Refused
- 9 Don't know

Universe Text: All family members age 5+ years

Skip instructions: cycle through all family members age 5+: <1-4,R,D> [go to next section]

Binge Drinking: A question on binge drinking added to the NHIS Core Module in 2014 for Sample Adults was modified for 2015 and continues in this modified form for 2016. The modification to the 2014 question, which had asked about alcohol consumption in a two-hour time period, changed the time frame for alcohol consumption from a two hour window to “an occasion.” This change made the NHIS question more similar to binge drinking questions on CDC and other federal and state health surveys.

Adult Select Items: This module, first included on the NHIS in 2013, continues for 2016. It contains questions to ascertain respondents' sexual orientation, embedded alongside questions about their neighborhood, computer use, sleep patterns, and mental health. Some questions were newly developed for this module, while others were moved into this section from other parts of the Adult Core Module. Limited nationally representative data are available on health disparities that involve the Lesbian, Gay, and Bisexual (LGB) populations. Many Healthy People 2010 objectives went unmeasured because most general health studies do not include questions on sexual orientation and those that do are usually targeted to a specific health-related issue or population subgroup. The objective of asking sexual orientation in the NHIS is to fill the tremendous gap that exists regarding knowledge of general health behaviors, health status, and health care utilization of LGB persons.

Child Health Status: A small number of follow-up questions have been added to the current core questions that ask if the Sample Child has ever been diagnosed with Autism, intellectual disability, and ADD/ADHD. The new follow-up questions ask if the child currently has the condition.

Methodological projects: Using the sample of respondents not set aside for MEPS, NHIS respondents may be recontacted for a follow-back survey several months after their initial interview. Such follow-back surveys in 2016 and 2017 will build on the findings from the previous two follow-back surveys that examined different modes of data collection, the impact of administering survey components to different respondents, and changes in health care coverage. Aimed at answering specific methodological questions and informing the 2018 questionnaire redesign, we will test new and/or updated questionnaire items, shortened topical areas, and compare the quality of information collected from different adult respondents.

Pending funding, a subsample of NHIS respondents may be identified to participate in an NHIS-embedded pilot test to assess the feasibility of integrating wearable devices into the NHIS data collection process. The aim is to determine the NHIS's ability to obtain objective health measurements, and to compare those measurements to the self-reported health information provided by respondents. A brief description of this project is provided in Attachment 4g. Because this test of wearable devices would be carried out as part of the regular NHIS interview, it would result in no additional burden to the public.

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, processing, and releasing data. CAPI usually reduces the average duration of interviews compared to a paper questionnaire with identical content.

A 2016 follow-back survey would continue the testing (that was begun with the NHIS follow-back survey in 2013) of employing self-administered web-based surveys with computer assisted

telephone interviewing and, possibly, mailed questionnaires. These survey collection modes would be supplemented with telephone interviewing as needed.

The pilot test of wearable devices to collect direct measures of health indicators would be of minimal respondent burden due to the passive nature of the data collection during the brief testing period. At the same time, wearable devices can provide valuable information that could lead to significant long-term reduction of respondent burden if wearable devices are implemented permanently on the NHIS. Aside from reducing the burden from recalling and answering questions about specific health-related information, the greater accuracy with which the health information could be collected would increase the usefulness of the resulting data to the policy and research communities, as well as the general public. Thus, wearable devices could be used to validate or replace NHIS survey questions, ultimately reducing participant burden and providing accurate and objective health measurements.

4. Efforts to Identify Duplication and Use of Similar Information

NHIS is DHHS's primary source of information regarding the U.S. noninstitutionalized population's health status, health care access, and progress toward achieving national health objectives.. The Core items of the NHIS are not duplicated in their entirety in any other national data system. In fact, other surveys borrow questions from the NHIS for new data collection mechanisms. To the extent that there is some overlap in content of the Core Module with other surveys, it is because it is necessary to ensure that the full range of covariates are included for complex analyses of data on the NHIS sample.

NCHS participates in interagency workgroups on mental health, sexual orientation, health insurance, and tobacco use that were established to harmonize content on major DHHS surveys.

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 health status of sexual minority populations. 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 population subgroups or persons with certain conditions. 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.

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

A 60-day Federal Register Notice was published in the Federal Register on 09/02/2015, Vol. 80, No. 170, pp. 53157 (see Attachment 2a). One comment was received (see Attachment 2b) and the standard CDC response was sent.

B. Other Consultations Outside the Agency

For the 2016 NHIS sample redesign, sampling experts at NCHS collaborated with their counterparts at the U.S. Census Bureau to develop a timeline and procedures for implementing the new sample. In 2012, an interagency group (NCHS and Census) created a milestone schedule for the sample redesign. Between 2013 and 2015, workgroups at NCHS and the Census Bureau conducted methodological and procedural research on the new sample, with specific focus on the new source of sample addresses (e.g., accuracy, geocoding quality, coverage of college dormitories, etc.) and the anticipated flexibility to alter overall sample size and/or shift sample allocations between States from year to year.

For the 2018 NHIS questionnaire redesign, outside consultations commenced in the fall of 2015 with an environmental scan of data users, in which primary uses of survey data were identified. This will be followed in mid-2016 with a second round of outreach, in which the scientific and policy communities will be asked to provide feedback on a draft questionnaire. For this latter activity, an IC will be submitted for clearance along with the draft questionnaire.

9. Explanation of Any Payments or Gifts to Respondents

No payments will be made to respondents in the main NHIS.

Permission is requested to employ monetary incentives in either or both the follow-back survey and pilot test of wearable devices to maximize response rates and respondent participation. The request for such incentives will be detailed when the projects are further developed and submitted for clearance. The follow-back survey would be a variation on the past two such studies.

10. Assurance of Confidentiality Provided to Respondents

The NCHS Privacy Act Coordinator has reviewed this request and has determined that the Privacy Act is applicable because information in identifiable form is being collected. The Privacy Act System of Records name is 09-20-0164 Health and Demographic Surveys Conducted in Probability Samples of the U.S. Population. The Office of the Chief Information Security Officer (OCISO) has a current copy of the Privacy Impact Assessment.

Confidentiality provided to respondents is assured by adherence to Section 308(d) of the Public Health Service Act (42 USC 242m) as follows (Attachment 1):

All information that 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.”

Overview of the Data Collection System

For the 2016 sample re-design, data collection procedures remain unchanged from those previously in use. Under an interagency agreement, 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 using laptop computers. Personal household visits may be supplemented with telephone data collection under certain circumstances: 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 800 trained interviewers, directed by survey supervisors in the 6 U.S. Census Bureau Regional Offices. Interviewers (also referred to as Field Representatives or FRs) receive initial and/or annual refresher training in common interviewing procedures, the concepts and procedures unique to the NHIS, and survey content changes.

To conduct the computer-assisted personal interviewing (CAPI), interviewers use official Census Bureau-furnished laptop computers equipped with Blaise software that presents the questionnaire on the computer screen. The CAPI 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. Publicly released data sets are available indefinitely on the NCHS website.

Responsibility for developing questions and monitoring field work in each of these areas is assigned to NCHS staff. Input to the design of questions is solicited from experts in a variety of organizations within the federal government, and from outside researchers and public health professionals.

Questionnaire Structure: The Core Module is repeated every year with little change; this allows for trend analyses and for data from more than one year to be pooled to increase sample size for analytic purposes. The Core Module contains three major parts: the Family Core (Attachment 4a), the Adult Core (Attachment 4b), and the Child Core (Attachment 4c). 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, specifically MEPS and NHIS follow-back surveys. Information collected on the Family Core for all family members includes: household composition and socio-demographic characteristics; tracking/recontact information; information for matches to administrative databases; and basic indicators of health status, health behavior, and health care services. It is at the beginning of the computerized instrument that the OMB statement is found. In previous years, the first part of the Family Core served as the screener questionnaire. In 2016 this screener questionnaire section has been removed, as screening is not being conducted in the 2016 data collection year. It may occur in subsequent years when such screening is needed to increase the number of interviews with persons in specific population groups.

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 himself or herself unless physically or mentally incapable. If there are children under 18 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 the family's whereabouts if they move.

Items of Information to be Collected

This clearance request is for continuing the previously approved Core and Supplemental Modules of the NHIS as well as new content. To put this request in context, a brief description of the overall questionnaire design is given here.

Five broad content domains and associated subdomains are covered by the Core Module: health status, health care services, health behavior, health care coverage, and socio-demographic characteristics. The subdomains are listed as follows:

Health status

- Conditions
- Injuries/Poisoning
- Activity limitations

Health care services

- Access to care
- Service utilization
- Barriers to care

Health Behaviors

- Tobacco product use
- Physical activity
- Alcohol consumption
- Obesity
- Sleep

Health Care Coverage

- Type(s) of coverage
- Cost and who pays
- Periods of noncoverage

Socio-demographics

- Household composition
- Race/national origin
- Education
- Income and assets
- Gender
- Sexual orientation

The previously-approved questions for the Core Module are included in Attachments 4a, 4b, and 4c.

Supplementary questions may be embedded within or attached to one of the principal sections (Family, Sample Adult, and Sample Child). The supplementary questions that will be administered in 2016 are shown in Attachment 4d. Flashcards used in the administration of the questionnaire are included in Attachment 4e. (Note that due to removal of the four flashcards pertaining to the Cancer Control supplement, the 2016 flashcards have been renumbered compared to the 2015 document. In addition, one flashcard changed slightly in the response categories for the number of employees working at the respondent's place of work.)

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 4f).

A description of the pilot test of wearable devices that is in its planning stages is included in Attachment 4g.

Compared to the 2015 instrument, two components are not being carried over into the 2016 NHIS: (1) the Incentives Test, and (2) the NHCCS Follow-back Survey. The reasons for this are as follows:

1. The Incentives Test was a one-time experiment to examine the impact on NHIS response rates from providing incentives for participating in the Family and Core modules of the survey. The experiment was completed and the data are being analyzed.
2. The 2015 NHCCS Follow-back Survey was a one-time project funded by money set aside for Affordable Care Act-related activities. It is currently underway.

Information in Identifiable Form

Information in identifiable form (IIF) is collected for linkage with other federal sources of data and to enable the MEPS and NHIS follow-back surveys to develop a sampling frame from NHIS 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

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 the two previous and any future follow-back surveys, as well as 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 staff at the U.S. Census Bureau), and NHIS' 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." Staff 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.

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 (Attachments 6a and 6b), 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 for the NHIS will be collected on official 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; 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. Researchers wishing to conduct analysis on variables not available in the public use data files may submit a research proposal to use the NCHS Research Data Center. Procedures for submitting the proposal and other important information can be found here <http://www.cdc.gov/rdc/>.

The 2016 questionnaires were approved by the Institutional Review Board (the NCHS Research Ethics Review Board) on June 12, 2015 (Attachment 7).

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. The potential sensitivity of questions was an evaluation criterion in determining content of the survey. The multi-purpose 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
- Sexual Orientation

Social Security Number and Health Insurance Claim Number: The last four digits of the social security number is asked on the NHIS questionnaire to allow linkage with administrative and vital records, such as the National Death Index (NDI). The NDI is a computerized central file of death record information. It is compiled from data obtained by NCHS from the State vital statistics offices. The data 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 last four digits of the social security number are 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 number that is their (or their spouse's) social security number 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 social security and health insurance claim number 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 his or her computer and read it to the respondent.

Citizenship Status: Because 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 has 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 on a flashcard:

- (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.

Sexual Orientation: Beginning in 2013, questions on sexual orientation were added to the NHIS. Extensive testing occurred prior to this addition to examine the impact of the questions on interview break-off, nonresponse or refusals, and other possible negative reactions. Multiple rounds of cognitive testing and three rounds of field testing were conducted. Treating the questions as sensitive by offering ACASI administration did not alter the results. Since introducing the questions on the NHIS in January 2013, there have been no complaints or negative outcomes.

12. Estimates of Annualized Burden Hours and Costs

A. Time Estimates

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

As shown below, the estimated overall average annual burden for 2016 to 2018, including the core questions, the supplement questions, the follow-back and other special projects, questionnaire redesign activities, and the reinterview component, follow-back is 49,000 hours.

Lines 1-3 of the burden table describe the various sections of the core questionnaire (Attachments 4a, 4b, 4c). Line 4 contains the supplemental questions (Attachment 4d). Line 5 covers the NHIS follow-back studies and other special projects (Attachment 4g). A small quality control resurvey of about 5,000 participating households is conducted, described in line 6 (Attachment 4f).

Estimated Annualized Burden Table

Form Name (Type of Respondent)	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)	Total Burden Hours
Family Core (Adult Family Member)	45,000	1	23/60	17,250
Adult Core (Sample Adult)	36,000	1	15/60	9,000
Child Core (Adult Family Member)	14,000	1	10/60	2,333
Supplements (Adult Family Member)	45,000	1	20/60	15,000
Methodological projects (Adult Family Member)	15,000	1	20/60	5,000
Reinterview Survey (Adult Family Member)	5,000	1	5/60	417
Total				49,000

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 Core 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.

For the 2016 and 2017 NHIS surveys, the average total burden is estimated to be about 49,000 hours, a net increase from 2015 of 1,367 hours resulting from the removal of the screener

questionnaire listed in Line 1 of the 2015 burden table (833 hours) and the addition of 2,200 hours in 2016 for methodological projects related to questionnaire redesign activities (e.g., follow-back surveys or split ballot experiments, or nonprobability web panels for testing new question wording, question placement, etc.), included in Line 5.

B. Cost to Respondents

At an average wage rate of \$21.00 per hour and an average length of interview of about 29 minutes for the 300,000 respondents (100,000 annually), the average cost per respondent is about \$10.29. (Wage rate information is from the Bureau of Labor Statistics: <http://www.bls.gov/ncs/ocs/sp/nctb1344.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
49,000	\$21.00	\$1,029,000

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

None.

14. Annualized Cost to the Federal Government

As shown in the table below, the total cost of the 2016 NHIS is estimated to be about \$42 million, which includes costs to NCHS directly and to its fieldwork contractor, the Bureau of the Census. For NCHS, the estimated cost for the 2016 data collection is about \$9 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 2016 NHIS will be about \$33 million, which is transferred to the Census Bureau through an Interagency Agreement.

Total 2016 Survey Costs	42 million
U.S. Bureau of the Census (Interagency Agreement)	33 million
Sampling	4.5 million
Survey Management	1.5 million
Field Operations	23.5 million
Data Editing	1.5 million

Programming and IT

2.0 million

National Center for Health Statistics

9 million

Approximately \$9 million of these costs are provided to NCHS through Interagency Agreements with survey sponsors.

15. Explanation for Program Changes or Adjustments

For the 2016 and 2017 NHIS surveys, the average total burden is estimated to be about 49,000 hours, a net increase from 2015 of 1,367 hours resulting from the removal of the screener questionnaire listed in Line 1 of the 2015 burden table (833 hours) and the addition of 2,200 hours in 2016 for questionnaire redesign activities included in Line 5. No changes in burden hours were made to Lines 2-4 (Attachments 4a-c).

Program changes that do not affect the burden hours include: addition of new Supplementary Questions (Attachment 4d), minor changes to Flashcards (Attachment 4e), and a new Reinterview instrument (Attachment 4f).

16. Plans for Tabulation and Publication and Project Time Schedule

The following are key activities and projected completion dates for the 2016 NHIS:

<u>Activity</u>	<u>Projected Completion Date</u>
Interviewer training	Three weeks prior to OMB approval
2016 data collection	12 months after OMB approval
Early release of selected estimates (Quarter 1)	Eight months after OMB approval
2016 data file available	18 months after OMB approval
Publication of Summary Statistics	Two years after OMB approval

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.