

Supporting Statement A for Request

The NHANES Longitudinal Study - Feasibility Component

OMB No. 0920-New

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The NHANES Longitudinal Study – Feasibility Component

SUPPORTING STATEMENT A

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Supporting Statement A

The NHANES Longitudinal Study – Feasibility Component

- The goal of the study is to assess the response rates of re-contacting, interviewing, and examining previously examined participants in the National Health and Nutrition Examination Surveys (NHANES), using a core module designed for the NHANES Longitudinal Study with a focus on chronic conditions.
- The intended use of the resulting data is to determine the feasibility of conducting a full-scale follow-up of previously examined NHANES adult participants. This longitudinal study, if feasible, could provide data to estimate the incidence of selected health outcomes in the U.S. population and relative risk related to other baseline data in a contemporary nationally representative cohort.
- A longitudinal follow-up design will be used to collect the data.
- The subpopulation to be studied are NHANES participants 20 years and older from the 2007-2014 survey cycles.
- Response rates and additional information related to response propensities and non-response bias will be obtained using appropriate statistical approaches, including models such as logistic regression.

This is a new request to conduct the NHANES Longitudinal Study – Feasibility Component. A two year clearance is requested.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through the National Center for Health Statistics (NCHS), shall collect statistics on the extent and nature of illness and disability; environmental, social and other health hazards; and determinants of health of the population of the United States (Attachment 1). Under this authorization, the National Health and Nutrition Examination Surveys (NHANES; OMB No. 0920-0950, Exp. Date 12/31/2019) have been conducted periodically between 1970 and 1994, and continuously since 1999 by NCHS, CDC. With a nationally representative sample of the civilian, non-institutionalized U.S. population, the NHANES program produces descriptive statistics on the health and nutrition status of the general population based on direct physical measurements. NHANES data have been the cornerstone for numerous national health and nutrition policy and surveillance activities.

The increasing prevalence of obesity and chronic diseases, including diabetes, cardiovascular and kidney diseases is an important public health issue and is propelling NCHS to conduct a longitudinal study of previously examined NHANES participants. By re-contacting these previous participants to obtain additional information about changes in their health conditions, exposure to risk factors, and utilization of healthcare since prior participation, we will be able to estimate the incidence of various chronic conditions such as hypertension, cardiovascular disease, obesity, diabetes and chronic kidney disease, and the relative risk of a wide range of outcomes with a nationally representative sample. This will be the first nationally representative cohort in more than two decades. The survey's extensive baseline data on health conditions, nutritional status, and risk behaviors will further allow us to identify, monitor, and clarify the longitudinal impact of new natural histories (earlier onset of metabolic risk) and risk factors on the development of these chronic conditions and associated morbidity. The information will enable us to track progress on national goals for prevention.

Not since the NHANES I Epidemiologic Follow-up Study (NHEFS; OMB No. 0920-0218, Exp. Date 12/31/1993), which was also conducted by NCHS, has there been a follow-up of a nationally representative cohort to assess the associations between baseline clinical, nutritional, and behavioral factors to subsequent morbidity and mortality. NCHS has prior experience conducting the follow-up of the NHANES I cohort in 1982-1984, but more than 30 years has passed. Since then, response rates in major federal surveys have declined and obtaining cooperation from the household population has become more difficult. Therefore, before attempting to launch a full scale data collection effort among all examined adults from NHANES 2007-2014, we propose conducting this feasibility study (the NHANES Longitudinal Study – Feasibility Component) to determine whether previously examined participants can be successfully traced, interviewed, and examined. In addition, we will evaluate the operational feasibility of the components currently planned for the future NHANES Longitudinal Study with a focus on chronic conditions and assess the performance of these components administered in the home setting. The proposed Feasibility Component is comprised of two elements: 1) a field feasibility test for the core module of the NHANES Longitudinal Study; and 2) a series of targeted methodological tests of additional components and procedures.

2. Purpose and Use of the Information Collection

For the field feasibility test, 800 baseline NHANES respondents will be sampled from the 2007-2014 NHANES examinees via a probability sample within 8 geographic clusters. The design is sufficient to obtain robust estimates of overall response and response by age group, race and ethnicity, and years since baseline. The components being considered for inclusion are a questionnaire and a home examination that includes: blood and urine specimen collection, weight, waist circumference, blood pressure measurements, and a monofilament assessment for neuropathy. Whenever possible, component protocols would follow those used in past cycles of NHANES. Test results from the home examination will be provided to the participants by mail several weeks after the exam. A proxy interview will be conducted for sampled participants who died prior to the re-contact via telephone. Please see Attachment 3a, Attachment 3b, Attachment 3c, and Attachment 3d for more details of each individual component for the proposed questionnaire and examination.

The primary goal of the field feasibility test is to assess how well we can locate and re-contact past participants, and determine individuals' willingness to participate in the data collection components as described above.

The specific objectives for the field feasibility test are to assess *whether*:

- Prior participants can be located and vital status determined
- Those located are willing to participate in an interview and an examination in their home
- Proxy respondents can be identified for those deceased, and are willing to participate in an interview via telephone
- The response rates for re-contact, interview, and examination are different by the number of years since baseline
- Respondents are able to provide details on hospitalizations and willing to give permission to obtain associated medical records
- The various aspects of field procedures (such as staff training, case load management, mailing schedule, appointment scheduling, and the report of finding system) are feasible
- The record retrieval protocol for hospitalization data is feasible across different medical facilities

The field feasibility test overall and subgroup-specific response rates will be examined by vital status (i.e., alive or deceased). The follow-up of all examined adults from NHANES 2007-2014 will be considered feasible if the field feasibility test overall response rate for the interview and examination among living participants reaches 70% or higher. Additional response rate analyses will be conducted among living participants, by the number of years since baseline, to evaluate the potential impact of time elapse on the follow-up. For deceased participants, the follow-up will be considered complete if the death has been confirmed by a death certificate or a proxy interview. Based on this definition, response rate assessments will be conducted for deceased participants as well.

In addition, detailed administrative data (i.e., paradata) about the follow-up process will be examined to better understand response propensities, the amount of effort needed to obtain responses from various types of respondents, the time lag between initial mailing contacts, appointment scheduling, and home visit completion, and the amount of effort needed to retrieve hospital records. Non-response bias assessments will be conducted to provide information on the potential differences between respondents and the non-respondents.

3. Use of Information Technology and Burden Reduction

The majority of the field feasibility test data are collected from respondents electronically. The field feasibility test uses survey information technology architecture (SITA) that supports fully automated and integrated information technology. SITA provides the field feasibility test with timely access to all data that are collected. With SITA, the field feasibility test data can be accessible at multiple sites including contractor facilities, field offices, laboratories, and NCHS headquarters. SITA supports: 1) survey planning and design, 2) data collection, 3) data receipt, control and quality assurance, 4) reporting of survey results to survey participants, 5) data review, editing and analysis, 6) tracking of survey respondents, and 7) generation of status reports on all aspects of the survey. Under the SITA, a Computer Assisted Personal Interview (CAPI) system with built-in probes, on-line help screens, and consistency checks will be used to reduce respondent burden and data entry errors.

There are no legal obstacles to reducing the burden through information technology.

4. Efforts to Identify Duplication and Use of Similar Information

NHANES (OMB No. 0920-0950, Exp. Date 12/31/2019) is the only national source of objectively measured health data capable of providing accurate estimates of both diagnosed and undiagnosed conditions. It is unique in that it combines personal interviews with standardized physical examinations, diagnostic procedures, and laboratory tests to determine the prevalence of major diseases and risk factors for diseases. A longitudinal follow-up of the NHANES participant will extend the utility of the NHANES data and provide valuable information on the incidence estimation of various health outcomes in the U.S. population and relative risk related to other baseline data.

The field feasibility test collects unique information to assess the feasibility of conducting a follow-up study of past NHANES participants. There are no other studies collecting these data.

The content of the feasibility component was developed with input from the Division of Diabetes Translation at the National Center for Chronic Disease Prevention and Health Promotion, CDC. In addition, NHANES program has maintained close collaboration with other data collection systems within the Department such as the National Health Interview Survey (NHIS; OMB No. 0920-0214, Exp. Date 12/31/2019), the Behavioral Risk Factor Surveillance System (BRFSS; OMB 0920-1061, Exp. Date 3/31/2018), and the Population Assessment of Tobacco and Health (PATH) Study (OMB No. 0925-0664, Exp. Date 05/31/2018) to reach the balance of avoiding duplicated efforts and harmonizing content on major DHHS surveys.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

With the exception of the Population Assessment of Tobacco and Health (PATH) Study (OMB No. 0925-0664, Exp. Date 05/31/2018), no nationally representative sample has been actively followed to identify, monitor, and clarify the longitudinal impact of risk factors on the development of morbidity related to lifestyle, socioeconomic conditions, and health care resources since the NHANES I cohort of 1971-1975. The effects of obesity, diabetes, and related metabolic risk factors are key examples of public health threats in need of contemporary longitudinal research. As the most comprehensive nationally representative survey for nutritional, behavioral, and metabolic risk factors in the world, a detailed longitudinal follow-up of participants of the NHANES presents a unique opportunity to clarify the contemporary determinants of chronic disease for the U.S. population. The proposed data collection for a field feasibility test is essential in the planning and implementation of this much needed longitudinal research.

Respondents are asked to respond to the field feasibility test only one time.

There are no legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines for 5CFR1320.5

This request fully complies with regulation 5CFR1320.5.

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

a. Federal Register Notice

In compliance with 5 CFR 1320.8(d), a notice soliciting comments on the collection for the NHANES Longitudinal Study – Feasibility Component was published in the *Federal Register* on May 23, 2016, volume 81, number 99, pp. 32330 - 32332. See Attachment 2a for a copy of the notice. One comment was received. See Attachment 2b for a copy of the comment and the corresponding agency response.

b. Efforts to Consult Outside the Agency

The development of the NHANES Longitudinal Study and its feasibility component has been communicated to current NHANES collaborators, including DHHS' NIH, FDA, and CDC, and USDA's Agricultural Research Service (ARS), Economic Research Service (ERS), and Food and Nutrition Service (FNS), and other non-government organizations. Information has been shared and discussed via numerous stakeholder meetings with these research collaborators. Once the response rate for the longitudinal study's feasibility component has been assessed, if it proves satisfactory, further planning activities would take place for the full NHANES Longitudinal Study, including an open proposal process to solicit additional content and feedback from above mentioned NHANES collaborators as well as the broader research community. Information Collection Requests would be submitted for approval using a non-substantive change request or full revision, as appropriate, for any future content or study activities.

9. Explanation of Any Payment or Gift to Respondents

To maximize response rates, NHANES participants have been provided with tokens of appreciation to recognize their effort and to encourage their examination participation since the 1970s. Respondents for the proposed field feasibility test are sampled from the NHANES 2007-2014, therefore, we anticipate that they will have reasonable expectations to receive incentive for participating in the follow-up study. The levels of incentive being requested are considered important to response rates, especially in light of the fact that there will be 3 to 10 years between the time the participants completed their baseline examination and the point of re-contact for this follow-up activity. The requested incentive and associated activities are described below.

Four weeks prior to the start of in-home visit at the survey location, a "Welcome back to the NHANES" package (Attachment 4a) will be mailed to the sampled participant to make the initial re-contact. A \$2 token of appreciation will be included in the package to encourage participation in the field feasibility test. According to a meta-analysis published in 2015, which quantified the dose-response relationship between monetary incentives and response rates among 40 household surveys across the past 21 years, the increase in response rate for a \$2 incentive in a mailed solicitation to participate was 10 percentage points.¹

¹ Mercer A, et al. How much gets you how much? Monetary incentives and response rates in household surveys. *Public Opinion Quarterly*, Vol. 79, No. 1, Spring 2015, pp. 105-129.

Instructions will be provided in the mailing package to encourage the participant to contact the study and register for the home visit. Participants will be given the options to complete the registration on-line or via telephone to confirm their contact information and appointment scheduling preferences. The registration process is estimated to take about 15 minute. Without proper contact information or pre-set appointment, ample survey resources may be spent on repeated contact attempts. Therefore, high compliance of the registration process will significantly increase the operational efficiency of the study.

During the in-home visit, the participants will be asked to complete an interview and a health examination. The home visit is estimated to take about an hour. An \$80 token of appreciation will be provided upon completion. Following the examination, they will be asked to collect a urine sample and mail it back to the lab. They will receive \$20 after returning the completed urine specimen. The level of these proposed incentives is consistent with the ones used in current NHANES for components with similar level of respondent burden.

Other than the \$2 bill mailed in the first letter, a debit card will be activated at the end of the home visit and used to provide each incentive.

For deceased participants, a proxy interview will be conducted with an identified proxy via telephone. No incentives will be provided for this proxy interview.

In summary, each participant may receive up to \$102 incentive for taking part in the proposed feasibility study. Detailed incentive schedule is listed in the table below by tasks.

Task	Incentive
Initial re-contact mailing	\$2
Completion of the home visit, including an interview and a health examination	\$80
Return of the urine sample	\$20

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The NCHS Privacy Act Coordinator and the NCHS Confidentiality Officer have reviewed this package and have determined that the Privacy Act is applicable. This study is covered under Privacy Act System of Records Notice 09-20-0164 (“Health and Demographic Surveys Conducted in Probability Samples of the U.S. Population”). A new Privacy Impact Assessment will be submitted, if it is determined that this project does not fall under the overall NHANES Privacy Impact Assessment which was submitted on July 20, 2016.

Confidentiality provided to respondents is assured by adherence to Section 308(d) of the Public Health Service Act (42 USC 242m(d)) and Section 513 of the Confidential Information Protection and Statistical Efficiency Act of 2002 (PL-107-347). The following assurance of confidentiality will be provided to respondents as stated in the consent form (Attachment 5):

“We take your privacy very seriously. All information that relates to or describes identifiable characteristics of individuals, a practice, or an establishment will be used only for statistical purposes. NCHS staff, contractors and agents will not disclose or release responses in

identifiable form without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA, Title 5 of Public Law 107-347). In accordance with CIPSEA every NCHS employee, contractor, and agent has taken an oath and is subject to a jail term of up to five years, a fine of up to \$250,000, or both if he or she willfully discloses ANY identifiable information about you. In addition, NCHS complies with the Cybersecurity Enhancement Act of 2015. This law requires the Federal government to protect its information by using computer security programs to identify cybersecurity risks against federal computer networks.

The Cybersecurity Act of 2015 permits monitoring information systems for the purpose of protecting a network from hacking, denial of service attacks and other security vulnerabilities. The software used for monitoring may scan information that is transiting, stored on, or processed by the system. If the information triggers a cyber threat indicator, the information may be intercepted and reviewed for cyber threats. The Cybersecurity Act specifies that the cyber threat indicator or defensive measure taken to remove the threat may be shared with others only after any information not directly related to a cybersecurity threat has been removed, including removal of personal information of a specific individual or information that identifies a specific individual. Monitoring under the Cybersecurity Act may be done by a system owner or another entity the system owner allows to monitor its network and operate defensive measures on its behalf.”

Information in Identifiable Form (IIF)

Information in identifiable form (IIF) is collected for linkage with other federal sources of data, to allow future re-contact of participants and to notify participants of health test results. The identifiable information includes:

- Name*
- Date of Birth*
- Social Security Number (SSN)*
- Medicare Health Insurance Claim Number*
- Mailing Address*
- Phone Numbers*
- Email Address
- Contact information for people close to the respondent*
- Employment Status*
- Medical Information and Notes
- Medical Records Numbers
- Death Certificates

Items in the above list with an asterisk (*) were collected during the baseline NHANES in 2007-2014. During this follow-up project, most of these items will be used to identify participants, confirm whether or not the right person was re-contacted and to conduct records linkages.

Medical information including dates will be collected about hospital stays only. Ambulatory care and emergency department visits were not included in the scope of this feasibility study due to funding constraints. Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), covered

entities (which includes most healthcare plans and healthcare providers) are permitted to disclose protected health information for research using one of two criteria: 1) with individual authorization or 2) without individual authorization under limited circumstances. In the field feasibility test, both mechanisms to meet HIPAA compliance will be used. For all participants for whom signed consent is obtained during an in-person interview, HIPAA compliant authorization will also be obtained. A waiver of authorization has been sought when the participants only allow us to reach them and conduct the interviews by telephone, and for participants identified as deceased. Please see “Supporting Statement B.2 Procedures for the Collection of Information” for more detailed on the protocol for obtaining hospitalization records.

More details on some IIF collected in field feasibility test are included in “A.11 Institutional Review Board (IRB) and Justifications for Sensitive Questions”.

It is the responsibility of all employees of NCHS, including NCHS contract staff, to protect and preserve all data in the NHANES Longitudinal Study – Feasibility Component (this includes all oral or recorded information in any form or medium) from unauthorized persons and uses. All NCHS employees as well as all contract staff have received appropriate training and made a commitment to assure confidentiality and have signed a “Nondisclosure Affidavit”. Staff of collaborating agencies are also required to sign this statement and agencies are required to enter into a formal Designated Agent Agreement with NCHS before access to non-public data is permitted. It is understood that protection of the confidentiality of records is a vital and essential element of the operation of NCHS, and that Federal law demands that NCHS provide full protection at all times of the confidential data in its custody. Only 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. The transmission and storage of confidential data are protected through procedures such as encryption and carefully restricted access.

NCHS policy requires physical protection of records in the field, and has delineated these requirements for the data collection contractor. The contractor also has its own policy and procedures regarding assurance of confidentiality and a pledge that all employees involved in NHANES must sign. The contractor provides all safeguards mandated by Privacy Act and confidentiality legislation to protect the confidentiality of the data. The contractor’s data security procedures comply fully with security requirements delineated by the Office of the Chief Information Officer (OCIO) of CDC.

Due to the methodological nature of the feasibility study, and the fact that the sample of this data collection, while demographically and geographically diverse, is not nationally representative and only of small size, the field feasibility test data will not be publically released. It will only be available to the public through NCHS Research Data Center (RDC). All outputs generated from RDC access are required to undergo the disclosure review to assure the confidentiality.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Self-reported and objective data of a sensitive nature are described in this section.

Social Security Number

Social Security Number (SSN) was requested of all participants at baseline in the household interview as a key item. The information was used to link administrative and vital records, such as the National Death Index (NDI), to the survey information. The last 4 digits of the SSN will be asked again as part of the verification module (Attachment 3b) in the feasibility test, the information will be compared with the data reported at baseline to confirm whether or not the right person was re-contacted.

Medicare Health Insurance Claim Number

Participants covered by Medicare were asked at baseline to provide the Health Insurance Claim Number. For participants who report coverage by Medicare at follow-up the Medicare Health Insurance Claim Number will be collected as well. This information will be used to link to Medicare records for further health research and to link with other records for possible re-contact of NHANES participants.

Permission to link is obtained from respondents as follows: "May I please see {your/Sampled Participant's} Medicare card to record the Health Insurance Claim Number? This number is needed to allow Medicare records of the Center for Medicare and Medicaid Services to be easily and accurately located and identified for statistical or research purposes. We may also need to link it with other records in order to re-contact {you/Sampled Participant}. Providing the Health Insurance Claim Number is voluntary and collected under the authority of the Public Health Service Act. Whether the number is given or not, there will be no effect on {your/his/her} benefits. This number will be held confidential." If asked, the interviewer will clarify that "The Public Health Service Act is Title 42, United States Code, Section 242K."

All questions and procedures have been reviewed by the NCHS Ethics Review Board (Attachment 6). The potential sensitivity of questions and procedures is an evaluation criterion in determining content of the survey.

12. Estimates of Annualized Burden Hours and Costs

This submission requests OMB approval for a feasibility study data collection over a 2-year period. The annual burden for each survey component of this project is shown in the table below. The estimated total burden for 2 years of the NHANES Longitudinal Study – Feasibility Component is 2,110 hours (or 1,055 annually), including a field feasibility test for the core module of the NHANES Longitudinal Study, a series of targeted methodological tests for additional components and procedures, and the retrieval of 720 hospitalization records.

The estimated average burden for the field feasibility test is 84 minutes per respondent (1.5 hours per respondent for 356 living participants and 35 minutes per respondent for 44 proxies of deceased participants, annually). Line 1 of the burden table describes the registration form that is applicable for both living participants and decedent proxies (Attachment 3a). Lines 2 represents burden for questionnaires and examination items collected among living participants during the home visits (Attachment 3b). Lines 3 describes the burden for collecting and mailing back a urine sample after the home visit (Attachment 3c). The burden for the questionnaire for proxies of deceased participants is described in line 4 (Attachment 3d).

Although permission will be sought from all field feasibility test participants, hospitalization records will be obtained only for up to 120 participants annually (240 participants over the 2-year period) to evaluate the record retrieval protocol for the study cohort among different hospitals. An average of 3 hospital stays per person is anticipated among this cohort, therefore, an estimated 360 requests (120 persons * 3 stays) will be made annually. The estimated burden for hospital record provider is 20 minutes per record and is described in line 5 of the burden table (Attachment 8b, Appendix 8b-2).

Up to 750 (or 375 annually) additional persons (non- field feasibility test respondents) may participate in tests of procedures, special studies, or methodological studies as resources permit (Attachment 9). As described in line 6 of the burden table, the estimated average burden for these special study respondents is 1 hour. The estimated total burden for one year for these special studies is 375 hours. A Change Request, non-substantive or full revision (as appropriate), will be submitted for clearance when the targeted methodological studies are further developed.

Estimated Annualized Burden Hours

Type of Respondent	Form	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
2007-2014 NHANES examinees, and proxies of deceased 2007-2014 NHANES examinees	Field feasibility test registration form - contact confirmation and scheduling preference	400	1	15/60	100
2007-2014 NHANES examinees	Field feasibility test home visit	356	1	1	356
2007-2014 NHANES examinees	Field feasibility test home urine collection	356	1	15/60	89
Proxies of deceased 2007-2014 NHANES examinees	Field feasibility test decedent proxy interview	44	1	20/60	15
Hospital record providers	Field feasibility test hospital records form	360	1	20/60	120
Adult volunteers (non- field feasibility test participants)	Targeted methodological studies	375	1	1	375
Total					1,055

Estimated Annualized Burden Costs

Type of Respondent	Form	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
2007-2014 NHANES examinees, and proxies of deceased 2007-2014 NHANES examinees	Field feasibility test registration form – contact confirmation and scheduling preference	100	\$23.23	\$2,323.00
2007-2014 NHANES examinees	Field feasibility test home visit	356	\$23.23	\$8,269.88
2007-2014 NHANES examinees	Field feasibility test home urine collection	89	\$23.23	\$2,067.47
Proxies of deceased 2007-2014 NHANES examinees	Field feasibility test decedent proxy interview	15	\$23.23	\$348.45
Hospital record providers	Field feasibility test hospital records form	120	\$17.47	\$2,787.60
Adult volunteers (non- field feasibility test participants)	Targeted methodological studies	375	\$23.23	\$8,711.25
Total				\$23,816.45

At an average hourly wage rate of \$17.47 per hospital record provider and \$23.23 per other person, the total annualized cost was \$23,816.45 for 1,135 respondents (400 feasibility field test respondents, 360 hospital record providers, and 375 volunteers for targeted methodological studies), or \$20.98 per respondent. This estimated cost does not represent an out of pocket expense, but a monetary value attributed to the time spent participating the study.

The wage rate is based on data from the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nat.htm). The average wage for office and administrative support occupations is used for hospital record providers. The average wage and salary income of all occupations is used for other respondents and volunteers since these respondents do not fall into a single economic or occupational category.

13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

None.

14. Annualized Cost to the Federal Government

This project is planned to last two years. Staff costs were primarily based on Division of Health and Nutrition Examination Surveys (DHANES) personnel costs, which were obtained from the NCHS Financial Management Office. A proportion of these costs are paid by funds transferred to the CDC budget from a collaborating agency. It is estimated that about 86 percent of study costs will be covered through this support outside of NCHS.

Estimated Survey Cost Per Year

Category	Annualized Cost
Equipment, data collection and processing, contracts, labs/readings	\$1,950,000
NCHS staff costs for planning, data analysis and overhead	\$426,000
NCHS printing, staff travel, supplies, etc.	\$25,050
Total	\$2,401,050

15. Explanation for Program Changes or Adjustments

This is a new data/information collection request.

16. Plans for Tabulation and Publication and Project Time Schedule

The following are key activities and projected time schedule for the feasibility field test:

Activity	Time Schedule
Advance packages sent to respondents at the first survey location	1-2 months after OMB approval
Start data collection	2-3 months after OMB approval
Complete field work	9-11 months after OMB approval
Hospital records retrieval	9-14 months after OMB approval
Complete lab tests	12-13 months after OMB approval
Data analysis	11-17 months after OMB approval
First publication of summary statistics	18 months after OMB approval

The primary analysis for the field feasibility test is to examine the overall and subgroup-specific response rates by participants' vital status (i.e., survivors or deceased). Please refer to Supporting Statement B.2. Procedures for the Collection of Information, Estimation Procedures section for more details on planned analyses.

NHANES longitudinal study feasibility component data will not be publicly released, however the data will be made available through the NCHS Research Data Center (RDC). Below is a brief summary of how we plan to use and disseminate the data/results from the study:

- a. The use of the data will be limited to methodological research, no national or population estimates will be produced from the feasibility study.
- b. Due to the methodological nature of the feasibility study – small sample size and not nationally representative - the field feasibility test data will not be publically released. It will only be

available to researchers through the NCHS Research Data Center (RDC). A review and approval of the research proposal is required for the RDC access. All outputs generated from RDC access are required to undergo disclosure review to assure confidentiality.

- c. The evaluation results from the feasibility study will be shared with collaborators in summarized tables. Similar to outside researchers, the collaborators can submit research proposals to request RDC access. No additional datasets are planned to be delivered or shared to collaborators.
- d. If successful, results will inform the design of a future full-scale longitudinal study. The NHANES longitudinal study feasibility component methodological and operational findings will be disseminated in presentations at national meetings, as well as through written reports/manuscripts in peer-reviewed journals and/or government publications.

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

The display of the OMB Expiration Date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.