

Supporting Statement A for Request
National Health and Nutrition Examination Survey

OMB No. 0920-0950

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Supporting Statement

NCHS National Health and Nutrition Examination Survey

- The goal of the study is to assess the health and nutritional status of adults and children in the United States.
- The intended use of the resulting data is to monitor public health and promote health by preventing and controlling disease and disability.
- The method to be used is a cross-sectional survey employing a stratified, multistage probability sample.
- The subpopulation to be studied is a nationally representative sample of the civilian, non-institutionalized U.S. population, all ages.
- The data will be analyzed data will be analyzed using appropriate statistical approaches and models such as logistic regression.

This is a request for revision to the National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0950, expires 11/30/2016). A two year clearance is requested.

The NHANES is a major ongoing source of information on the health and nutritional status of the civilian, non-institutionalized population of the United States. It is conducted by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC).

This revision request is submitted specifically to:

- add the collection of waist circumference on 3000 participants in 2016,
- extend the expiration date until the end of 2017 in order to allow completion of the 2015-2016 data collection
- continue conducting special studies that allow refinement in NHANES methods, and
- add additional hours for special studies.

The protocol for the ongoing 2015-2016 data collection will not change (except as noted above).

A. Justification

1. Circumstances Making the Collection of Information Necessary

Authorization

Four public laws authorize or necessitate the collection of information about the health of the American people. Excerpts of these laws are in Attachment 1.

- a) Section 306 of the Public Health Service Act (42 U.S.C. 242k) directs the National Center for

Health Statistics to collect statistics on subjects such as: the extent and nature of illness and disability of the population; environmental, social and other health hazards; and determinants of health.

- b) Section 4403 (Joint Nutrition Monitoring And Related Research Activities) of the Food, Conservation, and Energy Act of 2008 (P.L. 110-234) specifies that the Secretary and the Secretary of Health and Human Services shall continue to provide jointly for national nutrition monitoring and related research activities carried out as of the date of enactment of this Act.
- c) The Food Quality Protection Act of 1996 (P.L. 104-170) requires the implementation of surveys to collect data on food consumption patterns of infants and children and data on dietary exposure to pesticides among infants and children.
- d) Title 21 – Food and Drugs, Chapter 9 of the Federal Food, Drug, and Cosmetic Act (21 USC 393) authorizes the collection of information to support the Food and Drug Administration’s objective to obtain current, timely, and policy-relevant consumer information to carry out its statutory functions.

2. Purpose and Use of the Information Collection

The major objectives of NHANES are:

1. To estimate the number and percentage of persons in the U.S. population and designated subgroups with selected diseases and risk factors,
2. To monitor trends in the prevalence, awareness, treatment and control of selected diseases,
3. To monitor trends in risk behaviors and environmental exposures,
4. To analyze risk factors for selected diseases,
5. To study the relationship between diet, nutrition and health,
6. To explore emerging public health issues and new technologies, and
7. To establish and maintain a national probability sample of baseline information

on health and nutritional status.

The NHANES consists of three primary methods of data collection: the NHANES examination, NHANES laboratory assessments and the NHANES interviews. This revision proposes:

- Adding a Waist Circumference (WC) Methodology Study to the NHANES examination

Methodological / Special Studies to be conducted during NHANES 2015-16 cycle

- It is proposed to add a study that will compare the current NHANES waist circumference (WC) measurement protocol with two others: one recommended by the World Health Organization (WHO) and the other from the Multi-Ethnic Study of Atherosclerosis (MESA) protocol. Of note, the MESA protocol will be done twice: as a coached self-measurement and as a health technician- measurement. The study population will be NHANES participants aged 20 and over who participate in the body measurements component in the Mobile Examination Center (MEC). A pilot study for this project was conducted from 05/30/2015 to 06/29/2015. The response rate for this pilot was 96% for coached self-measurement and 94% for all other measurements done as part of the body measurement component (NHANES-WC, WHO-WC, and MESA_WC) (Attachment 12). The number of participants involved is expected to be approximately 3000 persons.

This project would be conducted over a 1 year period (or over 2 years if necessary in order to obtain the target number of participants). Full scale implementation in 2016 is the desired goal. This would be a one-time methodology study, not an ongoing project. The data would be used to create cross-over calibration equations to facilitate comparing the different methods of measuring waist circumference, compare WC measurement values obtained by different methods, and compare abdominal obesity classification agreement among the methods.

Special Studies and Additional Health and Nutrition Examination Studies

We are requesting an additional 1,000 respondents to conduct special studies, with an estimated 3 hours of burden per respondent. Currently we have approval for 2,500 respondents annually. The request to increase the approved special study respondent sample to 3,500 is being made to ensure that NHANES can continue to conduct special studies with sample sizes that are adequate for statistical analysis (even when conducting multiple special studies in the same year).

3. Use of Information Technology and Burden Reduction

The majority of NHANES data are collected from respondents electronically. NHANES uses survey information technology architecture (SITA) that supports fully automated and integrated information technology. SITA provides increased capabilities that allow processing of complex data with significantly less editing than in previous NHANES surveys.

SITA provides NHANES with access to all data that are collected, much of which is available in real-time. The nature of the survey requires that data be accessible at multiple sites including contractor facilities, MECs, 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) generation and documentation of public use data products, 7) tracking of survey respondents and 8) generation of status reports on all aspects of the survey.

There are no legal obstacles to reducing the burden.

4. Efforts to Identify Duplication and Use of Similar Information

NHANES is a unique source of health information on the U.S. population. Each year health interview and examination data are obtained. There are no other studies that collect the detailed health, dietary, laboratory and examination data that NHANES does. Duplication of effort is avoided through contacts and discussions with numerous Federal Government agencies during the content development and planning stage of NHANES. A specific example of this can be seen with regards to the tobacco-related data collected in NHANES. NHANES is the only survey (outside of the FDA-NIDA PATH survey) to collect biomarkers of tobacco exposure and tobacco constituents. Laboratory content in common with PATH is by design. Additionally, NCHS's National Health Interview Survey (NHIS) has been participating in Departmental collaborations regarding tobacco-related work. As part of the household interview, NHANES has maintained close collaboration with NHIS, and continues administer the majority of its NHIS tobacco related questions. The organizations contacted are listed in Attachment 3 of this clearance request.

5. Impact on Small Businesses or Other Small Entities

Only individuals will be asked to participate. No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

The continuous nature of the NHANES is necessary for several reasons. First, many of the data items collected in the NHANES are used for annual tracking of health events and circumstances, including tracking of the National Objectives for Health Promotion and Disease Prevention. 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. Third, nutrition monitoring legislation explicitly calls for continuous coverage to monitor nutrition changes as they occur (see Attachment 1). Fourth, a continuous survey is more cost effective because it makes possible a stable field 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 NHANES.

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

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

This data collection 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 NHANES was published in the Federal Register on September 8, 2015, volume 80, number 173, pp. 53799 - 53801. See Attachment 2a for a copy of the notice. One public comment was received. See Attachment 2b for a copy of the response.

b. Outside Consultation

The content of NHANES is developed with input from numerous DHHS agencies (including NIH, FDA, and CDC), several USDA entities (ARS, ERS, and FNS), other Federal agencies, non-government organizations, and individuals. The DHHS Data Council has been kept informed of the future NHANES plans. The DHHS Office of the Assistant Secretary for Planning and Evaluation has been briefed about the NHANES. Additionally, NCHS's Board of Scientific Counselors has been informed of future planning. Also, NHANES investigators are working with the National Household Interview Survey (NHIS) investigators, as well as other agencies including FDA, NIDA and NCI who have been following the Departmental activities in areas such as work related to tobacco issues.

NHANES is a collaborative undertaking. Broad input is sought from data users and interested parties to maximize the utility of the survey data. Extensive consultations occur in meetings with NHANES collaborators and interested agencies. A formal research proposal solicitation process occurs prior to content planning and development.

The major efforts taken to support collaboration processes are described below. New content proposals were solicited for the 2015-2016 data collection cycle by publishing the proposal guidelines on the NHANES website. Members of the NHANES user community received letters inviting them to submit research proposals. Correspondence was sent to dozens of persons who have expressed interest in being kept informed of NHANES activities. Over 18 proposals were received in response to this solicitation.

NCHS staff made numerous presentations throughout the year at major medical and public health professional meetings as well as internal meetings organized by Federal agency research staff. The meetings provide an excellent forum for updating stakeholders on survey research activities and data products.

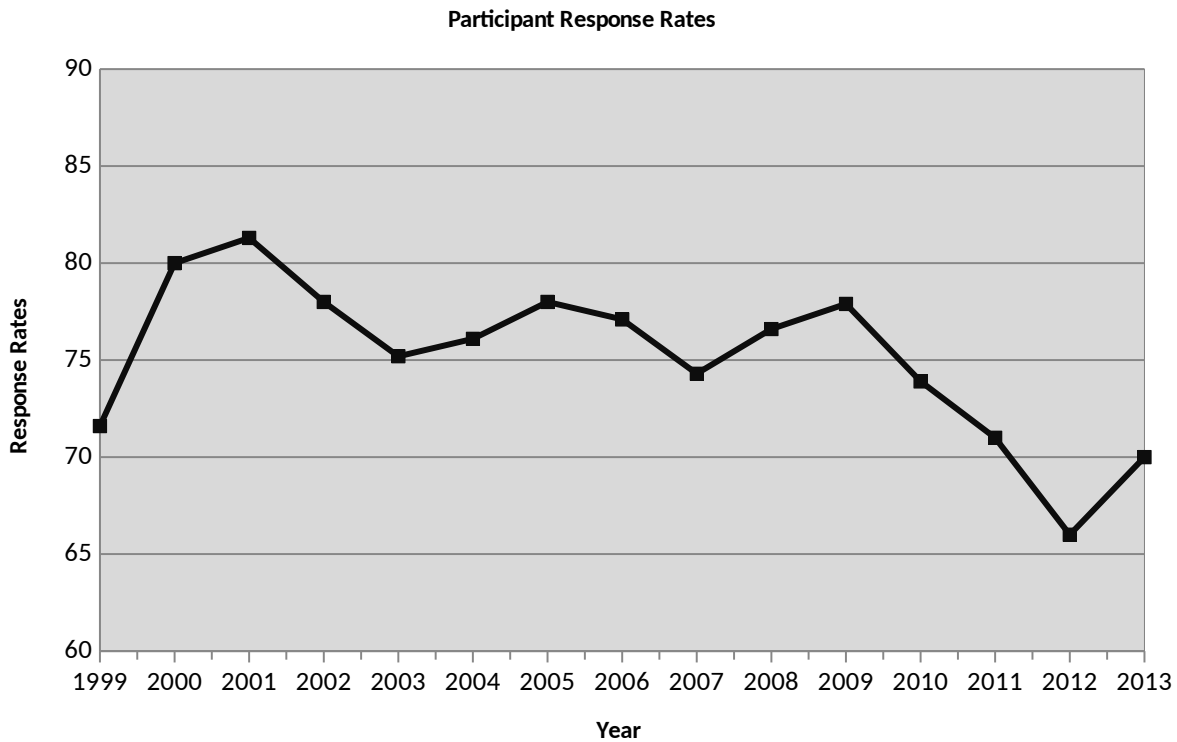
9. Explanation of Any Remuneration to Respondents

To maximize response rates for the examination, NHANES participants have been remunerated for their examination participation since the 1970s. Remuneration began after a study was conducted to test the effect of remunerating sample persons who participated in NHANES I. The response rate for those who were told they would receive remuneration was 82%. The response rate for those who were not told they would receive remuneration was 70%. Results of the study were published as "A Study of the Effect of Remuneration Upon Response in the Health and Nutrition Examination Survey, United States," Vital and Health Statistics, Series 2-No.67. During NHANES II another study was conducted, this time on the effect of increasing remuneration. It showed that those who were told they would receive \$20 after their examination had an examination rate of 79% while those who were told they would receive \$10 had an examination rate of 74%.

In NHANES III (1988-94) differential remuneration was successfully used to get participants to come to the examination session (morning, afternoon, or evening session) they were randomly assigned to. In prior NHANES, much data were lost due to failure of the participants to attend the randomly assigned session.

Continuous NHANES began in 1999 and the response rate was only 72%, therefore a remuneration study was undertaken in 2000. The basic comparison groups were the current level of remuneration plus a level approximately 50 percent higher. After 5,900 observations the overall response rate was the same in both groups. Interviewers were not blinded to the remuneration and their primary objective is to get the participant to the examination center. Comments made during the debriefing suggested that interviewers spent more time convincing the lower remuneration group to be examined.

The response rates for participants examined for 2012 and 2013 were 66% and 70% respectively. The response rates to the examination from 1999-2013 are presented in the graph below.



Below are the 2015-2016 NHANES remuneration rates. They are the same as those in 2014.

Examination incentive

Subgroup	2013-14 Incentive
16 and older assigned session	\$125
16 and older not assigned session	\$90
12-15 assigned session	\$75
12-15 not assigned session	\$60
Under 12	\$40

Post-primary examination incentive

Dietary Phone Follow Up	-	\$30
HPV oral specimen collection at home		\$50

If a family has one or more children under the age of 16 and no parent/guardian has been selected into the sample, a \$20 incentive is provided to accompany the child(ren) to the MEC. If participants must hire a sitter to care for children, elderly, or handicapped persons so that the participant can leave their home to be examined in the MEC, they are reimbursed at \$5.25 an hour up to 6 hours for a sitter. Participants also receive a transportation allowance for driving to the MEC, or for when a taxi is provided. It is proposed to implement this transportation allowance ahead of the MEC exam to improve the number of low income participants who keep their MEC exam appointments in the last two weeks of a MEC location. This project will only be

conducted among participants who have demonstrated commitment to the survey by having already completed the home interview and having already scheduled their MEC appointment.

Participant transportation allowance

TRANSPORTATION ALLOWANCE 2007–2014		
SP Transportation Allowance Mileages to MEC	Cities	Rural Areas
<16 miles	\$30	\$25
16–30 miles	\$45	\$40
31–59 miles	\$55	\$50
>60 miles	\$70	\$65

Other efforts are made to maintain and increase response rates on a day-to-day basis (See Section B. 3. Methods to Maximize Response Rates and Deal with Nonresponse).

Potential remuneration changes may be requested during the 2015-16 NHANES. In the future, it may be necessary to test methods to encourage more participants to accept weekday MEC appointments, to avoid overly crowded exam sessions. Currently, weekend appointments are frequently filled within the first two weeks at an exam site. As more participants are scheduled for exams, the already full weekend exam sessions may become overbooked with participants who are only available on weekends. Overbooking can result in incomplete data due to not having enough time to get all participants through their schedule of exams. Finding incentives to encourage participants to accept a weekday examination will ease the strain on the weekend sessions and increase the likelihood of having complete data on everyone who is MEC examined. NCHS is instituting and considering other non-monetary mechanisms to shift more appointments to weekdays. For example, modifying exam sessions hours on select days of the week to avoid participants having to travel during rush hours or changing exam schedules so that some sessions include the lunch hour to reduce the amount of leave participants might have to take off from work. If NCHS is unsuccessful in shifting more appointment to weekdays we may return to OMB with a change request for differential remuneration based on the day of the week. That is, offering higher remuneration for weekday MEC visits than for weekend appointments to make a weekday appointment more attractive to participants with schedules flexible enough to attend either a weekend or weekday MEC session.

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 Privacy Impact Assessment was submitted on June 20, 2013.

The Privacy Act of 1974 (5 U.S.C. 552a) “requires the safeguarding of individuals”, and Section 308(d) of the Public Health Service Act (42 U.S.C. 242m) requires the safeguarding of both individuals and establishments against invasion of privacy. Contractors who collect information identifying individuals and/or establishments must stipulate the appropriate safeguards to be taken regarding such information. The Privacy Act also provides for the confidential treatment of records of individuals, which are maintained by a Federal agency according to either

individual's name or some other identifier. This law also requires that such records in NCHS are to be protected from "uses other than those purposes for which they were collected."

The confidentiality of individuals participating in NHANES is protected by section 308(d) of the Public Health Service Act (42 USC 242m), which states:

"No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section...306,...may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and (1) in the case of information obtained in the course of health statistical or epidemiological activities under section...306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form..."

In addition, legislation covering confidentiality is provided according to section 513 of the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA) (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."

Consequently, all information collected in NHANES will be kept confidential, with an exception for suspected child abuse.

Overview of the Data Collection System

For the 2015-16 NHANES a contractor will carry out the data collection. The Contractor's responsibilities include the following activities.

- makes advance arrangements for each location
- sets up and maintains field offices and examination centers
- translates all questionnaires as required
- hires and trains field staff
- creates procedure manuals and training programs
- conducts all interviews in the households
- performs all interview and examination procedures in the examination centers
- designs and carries out quality control procedures and
- transmits interview, examination and laboratory data to NCHS

Extensive details on the data collection procedures are included in Supporting Statement section "B. 2. Procedures for the Collection of Information" and in the referenced attachments.

The following is a summary of the attachments related to the data collection procedures.

A pre-Advance Letter postcard and an Advance Letter (Attachment 4)
Household Screener Questionnaire (Attachment 8),
Household Relationship Questionnaire (Attachment 8),
Household/Family Questionnaire (Attachment 8)
Household Sample Person Questionnaire (Attachment 8)
MEC Data Collection Forms (Attachment 8)
Interview Informed Consent (Attachment 5)
Examination informed Consent (Attachment 5)
Stored Specimen Consent (Attachment 5)

Items of Information to be Collected

NHANES consists of the examination, conducted in the Mobile Examination Center (MEC), laboratory analytes, the household interview and follow-up activities, which take place after the MEC exam. Additional information about the information collected in the examination, laboratory assessments and interviews is shown below.

NHANES Examination

- Cardiovascular Health
- Diabetes Mellitus
- Dietary Assessment
- Oral Health
- Hearing
- Body composition
- Osteoporosis

NHANES Laboratory Assessments

- Renal and hepatic function
- Environmental Chemical Exposures
- Infectious Disease and Immunization Status Assessments
- Nutritional Status
- Biologic Specimen Banking

The NHANES Interviews

- Demographic Information
- Food Security And Nutrition Program Participation
- Dietary Supplement (DS) Use
- Prescription Drug Use
- Mental Health
- Weight History, Weight Self Image and Weight Related Behavior
- Alcohol Use
- Cigarette and Tobacco Use
- Reproductive Health and History
- Pubertal Maturation

Information in Identifiable Form (IIF)

Information in identifiable form (IIF) is collected for linkage with other federal sources of data, to

allow future recontact of participants and to notify participants of health test results. The identifiable information includes:

- Name
- Date of Birth
- Social Security Number (SSN)
- Medicare Beneficiary Number
- Mother's Maiden Name
- Name of mother on birth certificate (including maiden name)
- Name of father on birth certificate
- Parent's relationship to child
- Child's date of birth
- Child's sex
- Child's place of birth (hospital, city, county/township, state)
- Mailing Address
- Phone Numbers
- Medical Information and Notes
- Employment Status
- Contact information for two people close to the respondent

More details on some of this information are found in "A.11 Justifications for Sensitive Questions".

The NHANES continues to collect personal identifying information, on a confidential basis, needed to re-contact respondents and to match respondents to administrative records such as the National Death Index. The ability to track respondents and match to other records greatly expands the usefulness of the data at very low cost. Only those NCHS employees, specially designated agents, and our full research partners, who must use the personal information for a specific purpose, can use such data.

An Advance Letter (Attachment 4) is mailed to each household in the sample segments announcing the impending arrival of an NHANES interviewer and explaining the confidential treatment of their responses. The informed consent documents for the interview, the examination and the stored specimens each repeat the confidentiality assurance (Attachment 5).

It is the responsibility of all employees of NCHS, including NCHS contract staff, to protect and preserve all NHANES data (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". Staffs 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 Information Resources Management Office of CDC.

It is NCHS policy to make NHANES data available via public use data files to the scientific community. Confidential data will never be released to the public. For example, all personal information that could be potentially identifiable (including participant name, address, survey location number, sample person number), are removed from the public release files. The NCHS Disclosure Review Board reviews all files that will be released, to assure that directly or indirectly identifiable data are not included.

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

The National Health and Nutrition Examination Survey is subject to annual review by the NCHS Ethics Review Board and is approved to continue data collection through 11/10/2016 (see Attachment 6).

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

a. Social Security Number

Social Security Number (SSN) of all participants, children through adults, is requested in the household interview as a key item. The information is used to link administrative and vital records, such as the National Death Index (NDI), to the survey information. Additionally, in 2015-2016 NHANES will continue to use the SSN to link with Food Stamp Program and Women, Infants and Children (WIC) Program administrative records from the USDA.

Permission to link is obtained from respondents as follows: "The National Center for Health Statistics will conduct statistical research by combining {your/his/her} survey data with vital, health, nutrition and other related records. {Your/SP's} social security number is used only for these purposes and the Center will not release it to anyone, including any government agency, for any other reason. Providing this information is voluntary and is collected under the authority of Section 306 of the Public Health Service Act. There will be no effect on {your/his/her} benefits if you do not provide it."

ONLY READ IF ASKED. [Public Health Service Act is title 42, United States Code, section 242k.]

b. CMS Health Insurance Claim Number

Participants covered by Medicare will be asked to provide the CMS Health Insurance Claim Number. This will be used to link to Medicare records for further health research and also to link with other records for possible recontact of NHANES participants.

Permission to link is obtained from respondents as follows: "May I please see {your/SP'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/SP}. Except for these purposes, the Department of Health and Human Services will not release {your/his/her} Health Insurance Claim Number to anyone, including any other government agency. 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 in strict confidence. [The Public Health Service Act is Title 42, United States Code, Section 242K.]”

c. Residency Status

Information about country of birth and length of residency in the U.S. is requested and may be sensitive for recent immigrants. This information is important in analyzing health and nutrition data because acculturation may be related to use of the health care system, diet, and health practices. Additionally, recent immigrants may not have access to health, nutrition, and income assistance programs that affect access to health care and health and nutrition status. Interviewers will be trained to reassure participants that the information is confidential and will be used for statistical reporting only.

d. Other Content

Some of the NHANES research topics include potentially sensitive questions or examinations. In the informed consent procedure, all sample persons are advised of the voluntary nature of their participation in the survey or in any of its content. Again during the physical examination, each sample person is reminded that he or she can refuse to answer questions or to undergo any parts of the examination they find objectionable.

All questions and procedures have been reviewed by the NCHS Ethics Review Board (formerly called the NCHS Institutional Review Board) (see Attachment 6). The potential sensitivity of questions and procedures is an evaluation criterion in determining content of the survey. The multipurpose nature of NHANES makes it necessary to exclude topics so sensitive that they may interfere with participation.

Questions and procedures thought to be of a sensitive nature are listed below. Most of these are questions commonly asked in health care settings. Within the Mobile Examination Center, answers to sensitive questions are obtained privately.

- i. Sexual behavior and sexually transmitted diseases: Several sexually transmitted diseases are part of the NHANES—herpes simplex I and II, HIV, hepatitis B and C, trichomonas vaginalis, chlamydia and human papilloma virus (HPV). Information is obtained through questionnaires, exams, and lab tests. It is essential to clarify risk factors and identify at-risk population subgroups associated with infection in order to plan and evaluate prevention programs. This requires self-reported information on sexual behavior combined with objective data on infection.

Questions on sexual activity are asked of males and females 14 years and older. The results of tests for sexually transmitted diseases will not be mailed to examinees for reasons of confidentiality. Examinees will be given a toll-free number they can call, with the use of a self-selected password, to obtain their results. These questions will be administered using ACASI methods in a private room.

- ii. Drugs, alcohol, and tobacco: Drug, alcohol, and tobacco use are risk factors for many of the health conditions studied in NHANES. Questions are asked in the MEC of persons 14 years of age and older concerning the use of alcohol, marijuana, and cocaine; participants 12 and older will be asked about alcohol consumption and tobacco use. Illicit drug use, tobacco, and alcohol questions are administered to youth 12-19 years of age using ACASI methods in a private room.
- iii. Reproductive health and menstruation: Questions on reproductive health history asked of females 12 years and older may be considered sensitive by some respondents. The interviews will be conducted in a private room in the mobile examination center by specially trained interviewers.

Age of first menstruation will be obtained for females 8 years and older. This question will be asked of parents of girls 8 to 11 years of age. Information on menarche for 8-11 years of age is necessary for interpretation of biochemical and hematological assessments. As a safety screen for the dual X-ray absorptiometry (DXA), a pregnancy test will be performed on menstruating females ages 8-11 and all females 12 through 59 years.

- iv. Mental health: Adolescents and adults of all ages will be asked a short depression screening module called the Patient Health Questionnaire or the "PHQ-9." The questions are taken from the depression module of the PRIME-MD, a self-administered questionnaire that was first used in clinical setting. The interviews will be conducted in a private room in the mobile examination center by specially trained interviewers.
- v. Male and female urologic health: Conditions such as urinary incontinence and gynecologic infections affect millions of Americans. The information collected in NHANES is critical to understanding the magnitude of these problems and their impact on health and quality of life. The interviews will be conducted in a private room in the mobile examination center by specially trained interviewers.
- vi. Pubertal Maturation: The pubertal maturation module, conducted among participants ages 8-19, may be considered sensitive by some respondents. These questions will be administered using ACASI methods in a private room.

In addition to standard informed consent procedures, designated staff at the MEC will meet with parents or proxies of children aged 8-17 years and participants aged 18 and 19 years regarding the Pubertal Assessment module. Parents and participants will be asked to read the appropriate Pubertal Maturation Assessment Informational Flyer (Attachment 11). The MEC physicians will be trained to share age and gender appropriate drawings with parents and participants as requested and to answer general questions regarding puberty. The designated MEC staff will record that the parents or participants were given the flyers and the opportunity to read the flyers, see the drawings, and ask questions. Participants will be blocked from the MEC Interview until this has been completed.

- vii. Human Papilloma Virus (HPV) Swabs: Women ages 14-59 years will be requested to collect a self-obtained vaginal swab. Men ages 14-59 will be requested to collect a self-obtained penile swab. The swabs will be used to test for HPV infection. Survey participants will perform the swab collection in a private bathroom after being instructed on how to collect by the physician.

In addition to standard informed consent procedures, designated staff at the MEC will meet with parents or proxies of children aged 14-17 years regarding the HPV swab collection. Parents will have the opportunity to review gender specific materials related to the self-collection (Attachment 11). Participants ages 14-17 will be blocked from the Physician's examination until this has been completed.

- viii. Future content: As discussed in the Responding to Emerging Public Health Issues, New Technology and Future Survey Options portion of section A.2., during NHANES, new content may be pilot-tested or added, as new diagnostic procedures become available or as new conditions emerge. This content will be handled in similar fashion to that discussed above in the introduction to this section (A. 11d Other Content). Information will be explicitly discussed in the informed consent document if the content is considered sensitive, and appropriate privacy and confidentiality safeguards included.

12. Estimates of Annualized Burden Hours and Costs

a. Time Estimates

This submission requests OMB approval for three years of data collection, specifically for the 2015-2016 NHANES and for data processing efforts through 2017. These data collections will occur within the context of ongoing NHANES data collection activities. The burden for each survey component of one complete survey cycle is shown in the table below. The estimated total burden for one year of NHANES is 36,025 hours, including screening, household interview, examination and follow-up interviews.

Annually, approximately 14,410 respondents participate in some aspect of the full survey (Attachment 8). About 9,200 complete the screener for the survey. About 210 complete the household interview only. About 5,000 complete both the household interview and the Mobile Exam Center (MEC) examination. The majority of people completing both the interview and examination also participate in a second dietary recall interview. Averaging the burden across all respondents, at these varying levels of participation, results in an average burden of 2.5 hours. (The respondents who participate in all aspects of the survey can expect an estimated burden of 6.7 hours as documented in the signed informed consent documents [attachment 5].)

Approximately 3,000 respondents may participate in a Waist Circumference Methodology Study. The estimated total burden for one year is 400 hours.

Up to 3,500 additional persons (including non-NHANES respondents) might participate in tests of procedures, special studies, or for methodological studies, if budgeted. The average burden for these special study/pretest respondents is 3 hours (Attachment 10). The estimated total burden for one year for special studies is 10,500 hours.

TABLE 1 – ANNUALIZED BURDEN HOURS AND COSTS

Type of Respondent	Form	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)	Total Burden Hours
Individuals in households	NHANES Questionnaire	14,410	1	2.5	36,025
Individuals in households	Waist Circumference Methodology Study	3,000	1	8/60	400
Individuals in households	Special Studies	3,500	1	3	10,500
Total					46,925

b. Cost to Respondents

The hourly wage rate of \$22.33 per person is based on income from wages and salary from the Bureau of Labor Statistics: http://www.bls.gov/oes/current/oes_nat.htm#00-0000. This wage rate for all persons was used since respondents do not fall into a single economic or occupational category. The total cost was \$1,100,311 or \$57.28 per respondent. (NOTE: There are no out-of-pocket costs to survey participants. Participants are remunerated for their time as well as for child care and transportation expenses.)

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

None.

14. Annualized Cost to the Federal Government

This project is a multi-year, continuous survey, with survey planning, data processing and analysis, and data collection occurring simultaneously. These figures are broad estimates based on past NHANES data collection budget estimates. Staff costs were primarily based on Division of Health and Nutrition Examination Surveys 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 collaborating agencies. It is estimated that about 30 percent of survey costs will be covered through this support from agencies outside of NCHS.

Table 1. Estimated survey cost per year

Category	Annualized Cost
Equipment, exam centers, data collection and processing, contracts, labs/readings	\$35,000,000
NCHS staff costs for survey	\$6,000,000

planning, data analysis and overhead	
NCHS printing, travel, supplies, etc. for NHANES staff	\$200,000
Total	\$41,200,000

15. Explanation for Program Changes or Adjustments

The new requested burden as a result of this submission is 46,925 hours, an increase of 3,400 hours. This increase represents 400 hours due to the newly added Waist Circumference Methodology Study and 3,000 additional hours added to the special studies line.

16. Plans for Tabulation and Publication and Project Time Schedule

The following are key activities and projected completion goals for the 2015-2016 NHANES:

Activity	Projected Completion
• Planning survey content	Nineteen months before OMB approval
• 2015-2016 data collection	Three years after OMB approval
• First public release of data	Three years and six months after OMB approval
• First publication of summary statistics	Three years and six months after OMB approval

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

We have several forms that are triplicate, NCR-type pages pasted into glossy, multi-page brochures, which require considerable advance time for printing. To save substantial printing costs, since 1999 OMB has granted an exception from printing the expiration date on these forms for data collection. We request that exemption be continued through the term of this clearance.

18. Exceptions to Certification for Paperwork Reduction Act Submissions.

There are no exceptions to the certification.