

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

This is a request for revision to the National Health and Nutrition Examination Survey (NHANES) to modify selected sections of the NHANES (OMB No. 0920-0950, expires November 30, 2015). A three 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:

- collect data for 2015-2016,
- conduct activities related to data collection/processing through 2017,
- conduct special studies to support data collection for 2017 and beyond,
- conduct non-response studies if needed.

Brief summary of planned changes for the 2015-2016 NHANES

This request includes obtaining clearance to conduct NHANES Sample Person Household and Family Interviews; Mobile Examination Center (MEC) interviews and dietary interviews; the NHANES examination; Laboratory assessments; and Telephone follow-up interviews and other follow-up activities for 2015-16.

Adding in 2015-16

- Cycling back from 2011-12 is the audiometry (hearing) examination component and questionnaire (AUQ) and laboratory tests for ferritin, transferrin receptor, and C-reactive protein
- Adding chromium and cobalt testing in whole blood, 2 smoking biomarkers, urine fluoride, 1 new volatile organic compound and 10 diisocyanate metabolites and urinary amines
- Adding collection of four additional oral HPV specimens in the home at 6, 12, 18 and 24 months after the first collection at the MEC
- Adding 6 questions from the 2015 NHIS on depression and anxiety

Cycling Out for 2015-16

- Cycling out are the physical activity monitor, taste and smell, cognitive function and upper body muscle strength (grip test) components.
- Laboratory assessment for celiac disease, pentachlorophenol, caffeine metabolites, omega-3-fatty acids, vitamin B12, methylmalonic acid, and hemoglobin adducts tobacco markers
- Questionnaire sections for taste and smell, celiac disease, psoriasis, creatine kinase and questions related to memory

A summary of additional changes to the questionnaire can be found on page 14

Requests for continued permission to conduct pilot or methodological testing for future NHANES will be submitted through non-substantive change requests. Special studies would be submitted for approval using a full revision or through a separate clearance request under a different OMB number.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The National Center for Health Statistics (NCHS), Division of Health and Nutrition Examination Surveys (DHANES), Centers for Disease Control and Prevention (CDC) is seeking a three-year approval to revise the National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0950, expires 11/30/2015)), and specifically to collect data for 2015-2016; to conduct activities related to data collection/processing for 2017; and to conduct special studies to support data collection for 2017 and beyond.

Background

NCHS has conducted a series of health and nutrition surveys since the early 1960s. The surveys are unique in that physical examination data are obtained from national samples of the U.S. population. The NHANES examination is conducted in mobile examination centers (MECs) that travel to fifteen survey locations per year. NHANES data have been the cornerstone for numerous national health and nutrition policy and surveillance activities.

The NHANES were conducted on a periodic basis from 1971 to 1994. NHANES became a continuous, annual survey program in 1999. Each year, a nationally representative sample of the civilian, non-institutionalized U.S. population, all ages, is interviewed and examined. The response rate for participants examined for 2013 was 70%. Innovative recruitment methods and remuneration have contributed to the high response rates over the years. However, it is increasingly difficult to maintain high response rates.

NHANES data are released in two-year cycles. One-year estimates may be produced if there is a compelling public health need and if one year of data can provide a reliable estimate. Data from NHANES are posted on the NCHS website at <http://www.cdc.gov/nchs/nhanes.htm>.

The continuous data collection requires that pilot tests of new or revised survey material be conducted during the ongoing data collection. NHANES will continue to request permission to conduct pilot and other methodologic studies through the use of the OMB nonsubstantive change procedures.

A major advantage of continuous NHANES data collection is the ability to address emerging public health issues and provide objective data on additional health conditions and issues. NHANES continues to report on major public health topics in a timely and efficient manner. Examples of contributions from NHANES data may be found on the NCHS/NHANES website.

The continuous survey design also makes earlier availability of the data possible. The first release of NHANES 2011-2012 data occurred in September 2013. In planning for 2015-2016 we have tried to take maximum advantage of the abilities of all software used in data collection to reduce data review and editing required after data collection. We hope to continue to meet our NCHS/NHANES data release date goals and have the greatest proportion possible of NHANES data released within a year of ending the data collection.

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.

The NHANES program, within NCHS, contributes to the mission of CDC by collecting objective data that are used to promote health by preventing and controlling disease and disability. CDC works with partners throughout the nation and the world to monitor public health, formulate and implement prevention strategies, develop health policies, promote healthy behaviors, and foster safe and healthful environments. In addition to the groups within the CDC, NCHS collaborates with over two dozen federal agencies to plan and fund the NHANES. The survey partners include numerous institutes of the National Institutes of Health, several programs within the U.S. Department of Agriculture, and the Food and Drug Administration. Proposals for adding content are open to all. Occasionally, a non-Federal collaborator proposes content that may be funded via the CDC Foundation. NHANES data are used to assess environmental exposures; evaluate nutrition program and policy impacts; and estimate prevalences of health risk factors, chronic conditions, and infectious diseases.

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. The purposes and uses survey content are detailed below.

NHANES Examination

NHANES Examination changes for 2015-16 include:

- Cycling back from 2011-12 the audiometry (hearing) examination component for participants ages 20-69.
- Target age for Oral Health component lowered to age 1.

See Attachment 8 for list of examination data collection forms for NHANES 2015-2016.

a. Chronic Conditions

NHANES continues to monitor trends in the prevalence and treatment of many common chronic conditions with content included on the examination, laboratory and questionnaires.

- Cardiovascular disease (CVD). The main elements of the CVD content on NHANES are measurements of blood pressure and blood total cholesterol, HDL-cholesterol, LDL-cholesterol, Triglyceride, and Apo (B) levels. A measure of aortic calcification will continue to be obtained on participants ages 40 and older during the dual X-ray absorptiometry (DXA) lateral scan.
- Diabetes Mellitus (DM). NHANES continues to monitor DM via fasting and two-hour blood glucose assessments, fasting insulin and measurement of glycohemoglobin (HbA1c). The household interview will include questions about diabetes awareness and treatment.
- Obesity. NHANES will continue to collect body measures of height, weight, circumferences and skinfold thicknesses (anthropometry) and Sagittal Abdominal Diameter. Body composition (lean and fat mass), will be measured by dual-energy X-ray absorptiometry (DXA) for those ages 8-59.

b. Dietary Assessment

All NHANES examinees are eligible for two dietary recall (DR) interviews. The first DR will be conducted in-person in the MEC and the second will be conducted by trained telephone dietary interviewers, during a follow-up phone interview. Additionally, a 24-hour intake of dietary supplements will be asked during both DRs.

c. Osteoporosis, Vertebral Fractures and Aortic Calcification

Hip and spine dual-energy x-ray absorptiometry (DXA) scans will continue for participants ages 40 and older. The scans will provide estimates of the prevalence of low bone mass and osteoporosis. Vertebral fracture risk and aortic calcification will be estimated through DXA scans of the lateral spine will also continue.

d. Oral Health (modified)

The target age group for the Oral Health component has been changed to participants ages 1 and older. (In NHANES 2013-14 the target age group was 2 and older.) The specific assessment a participant receives is dependent on their age. NHANES will continue to collect information on tooth retention and loss, tooth decay, dental restorations, dental fluorosis, and dental sealants. Periodontal health status will be cycled out. A rinsed specimen to test for oral Human Papilloma Virus (HPV) infection and Dental Fluorosis Imaging (DFI) will continue in 2015-2016.

e. Audiometry (new)

The target age group for the audiometry component is participants 20-69 years old. The rationale for returning to testing adults (20-69 years) is to provide updated, estimates of the degree of hearing impairment in the U.S. population of working age. These data are central to developing and implementing national hearing loss programs. Because audiometry alone may not be sensitive enough to detect middle ear disease, tympanometry is also conducted to provide an estimate of tympanic membrane compliance.

f. HPV swabs in males and females

Human papilloma virus (HPV) infection is one of the most common sexually transmitted infections in the U.S. Estimates of the prevalence of HPV infection in females via vaginal swabs have been part of the NHANES content since 2002 and in males since 2013.

NHANES Laboratory Assessments

Laboratory Assessment changes for 2015-2016 include:

- Cycling out testing for celiac disease, pentachlorophenol, caffeine metabolites, omega-3 fatty acids, hemoglobin adducts tobacco markers, vitamin B12 and methylmalonic acid (MMA).
- Adding laboratory assessments for urine fluoride, 10 diisocyanate metabolites and urinary amines, serum ferritin and transferrin receptor, C-reactive protein, one urinary VOC, one serum aldehyde, and whole blood cobalt and chromium measurements.
- Adding collection of four additional oral HPV specimens in the home at 6, 12, 18 and 24 months after the first collection (MEC).

See Attachment 7 for a detailed list of planned laboratory tests for NHANES 2015-2016.

a. Urine assessments

Urine Flow Rate

The urine excretion rate of an analyte is a more accurate measure of the exposure to environmental chemicals. The urine excretion rate (mg/min) is the product of the urine flow rate (mL/min) and the urine analyte concentration (mg/mL). Participants ages 6 and older will be asked to record their time of last void before coming to the MEC and then asked to void in the MEC where the time of collection and volume of the urine will be recorded and a urine flow rate will be calculated.

b. Environmental Chemical Exposures

The NHANES environmental health laboratory assessments were expanded in 1999 in collaboration with the Division of Laboratory Sciences (DLS), National Center for Environmental Health (NCEH). It now includes more than 250 measures of environmental chemicals or metabolites in blood and urine specimens collected from survey participants. These NHANES data are the cornerstone of the CDC publication, The Fourth National Report on Human Exposure to Environmental Chemicals (URL: <http://www.cdc.gov/exposurereport/>). The most recent report, published in February, 2012 includes 246 chemicals.

In general, within classes of chemicals, analytes new in 2015-16 were added to the protocol because either a method became available to measure the analyte and/or an analyte was added to a panel that was already on the protocol.

Note that selected categories of environmental chemicals are analyzed using pooled specimens (See Attachment 7). This is done because of the expense of measuring the compounds in hundreds of subjects and because a high proportion of results are below the limit of detection (LOD) for some chemicals.

The environmental analytes include the following chemical categories (**unless noted there are no changes in the chemicals within a category for 2015-16**):

- Tobacco biomarkers (See changes below)
- Metals (See changes below)
- Phthalates and phthalate alternatives
- Polycyclic aromatic hydrocarbons (PAHs)
- Non-persistent pesticides (organophosphate insecticides, pyrethroid pesticides)
- Other pesticides/insect repellents
- Perfluorinated compounds
- Environmental phenols and organochlorine pesticides
- Antiseptics

- Polychlorinated and polybrominated dibenzo-p-dioxins and dibenzofurans
- Polychlorinated biphenyls (PCBs)
- Polybrominated diphenyl ether
- Polychlorinated naphthalenes
- Volatile organic compounds (See changes below)

- Other

The uses of the NHANES environmental exposure information by the public health community include the following:

- to determine the types of chemicals and concentration levels to which Americans are exposed
- for chemicals with a known toxicity level, to determine the prevalence of persons above that toxicity level (e.g., blood lead > 10 µg/dL)
- to establish reference ranges that may be used by state and local public health physicians and scientists to determine whether an individual or group has an unusually high exposure
- to assess the effectiveness of efforts to reduce exposure to specific chemicals

- to determine whether exposure levels are higher among minorities, children, women of childbearing age, and other vulnerable groups
- to observe time trends in the levels of exposure within the population
- to set priorities for human health effects research

Metals

Numerous metals are measured in the urine, whole blood and serum of NHANES participants. In 2015-2016 the only change is to add measurements of chromium and cobalt levels in whole blood.

Other pesticides/herbicides

Serum pentachlorophenol will be dropped in 2015-2016.

Volatile organic compounds (VOC) (blood and urine):

The VOCs measured in blood and urine for 2013-14 will continue in 2015-16. N-acetyl-S-(1-cyano-2-hydroxyethyl-L-cysteine, a urinary VOC, is being added to the protocol.

Other tobacco biomarkers: On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act, which gave the Food and Drug Administration regulatory authority over tobacco products, were signed into law. Significant parts of the legislation are focused on setting product standards. To successfully evaluate the impact that product standards might have on the exposure of smokers a system needs to be in place to monitor the exposure of smokers. The tobacco biomarkers, unless otherwise stated, are measured in a 1/3 NHANES subsample. In 2011 only about 15 percent of the adult NHANES participants were cigarette smokers. To increase the sample size of smokers for these chemicals all self-reported cigarette smokers within the other two 1/3 subsamples will be included in the laboratory analysis.

The categories of tobacco biomarkers included are:

- Cotinine and Nicotine Analogs
- Aldehydes
- Aromatic amines
- Heterocyclic amines
- Tobacco-specific nitrosamines
- N-nitrosamines

Heterocyclic amine hemoglobin adducts will be cycled out. n-Hexanal and isobutyraldehyde aldehyde will be added.

c. Infectious Disease and Immunization Status Assessments

In 2015-16 penile swab for human papilloma virus (HPV) in males ages 14-59 and urine trichomonas in participants 14-59 will continue.

Laboratory tests for the following infectious diseases remain unchanged from 2013-14:

- Trichomonas vaginalis
- Chlamydia trachomatis
- Hepatitis profile

Herpes simplex 1 and 2
Human immunodeficiency virus
HPV (Oral rinse (collected at MEC), vaginal and penile swab)

To better characterize the natural history of HPV oral infection NHANES will collect four additional oral HPV samples from NHANES participants who provided a specimen during their MEC examination. These four will be obtained via mail at 6, 12, 18 and 24 months after the MEC examination. Response rates will be evaluated after each mailing to determine if the next data collection should take place.

d. Nutritional Biochemistries, Hematologies and other nutrition related analytes

Laboratory tests for the following nutrition biomarkers remain unchanged from 2013-14:

Complete blood counts
Serum and red blood cell folate
Standard biochemical profile
Serum lipids
Urinary iodine
Vitamin D
Plasma and water fluoride

Serum ferritin, transferrin receptor and CRP will be cycled back in to monitor iron deficiency among young U.S. children (aged 1-5 years) and females of childbearing age (aged 12-49 years).

e. Biologic Specimen Banking

Serum, plasma and urine continue to be stored for future research. The availability of stored biologic specimens from a representative sample of the U.S. population provides the scientific research community with a potential resource for the measurement of new and evolving laboratory tests for emerging diseases, risk factors, and environmental exposures. NCHS solicits proposals for use of the stored specimens. A technical panel will review and approve all proposals. All uses of stored specimens are subject to review and approval by the NCHS Ethics Review Board and the NCHS Confidentiality Officer. All unused serum from laboratories will be stored for potential additional analyses.

f. Other laboratory

Laboratory tests for the following biomarkers remain unchanged from 2013-14:

Standard biochemical profile (kidney, liver function)
Serum total testosterone levels
Serum estradiol
Serum sex hormone binding globulin

Urinary Fluoride will be added to the protocol.

Urinary Fluoride

The purpose of adding urine fluoride to NHANES is to compare and correlate this assay with the plasma and water fluoride currently measured in NHANES. The assay

will be collected on a one-third sample for participants aged 6 years and older.

The NHANES Interviews

The topics presented in this section are questionnaire data, collected as stand-alone components or to complement one or more NHANES examination or laboratory components. The questions are asked in the home or the MEC. Questionnaire changes are summarized in the following table. Details about select sections follow. The complete questionnaires are found in Attachment 8. The table of contents lists each questionnaire section by component name and corresponding 3 letter component abbreviation.

Most sections of the NHANES questionnaire remain unchanged from 2013-14. The tables below summarize all changes for 2015-16 with a brief description of the change and rationale for it. Below the table is some discussion of specific sections.

Changes in Questionnaire for 2015-16

Sample Person Questionnaire

Component Name and ID (3 Letters)	Descriptions
Medical condition (MCQ)	<ul style="list-style-type: none"> • Removed 2 questions related to psoriasis that cycled out • Removed 2 questions related to cognitive function that cycled out • Removed 2 questions related to Celiac disease that cycled out
Kidney Conditions (KIQ)	<ul style="list-style-type: none"> • Cycled out one question and replaced with one question related to number of kidney stone episodes within past 12 months
Disability Status (DLQ)	<ul style="list-style-type: none"> • Added 6 new questions (3 anxiety questions and 3 depression questions) to be identical with NHIS questionnaire
Blood Pressure and Cholesterol (BPQ)	<ul style="list-style-type: none"> • Cycled out 3 questions related to home blood pressure measurement
Osteoporosis (OSQ)	<ul style="list-style-type: none"> • Added 1 question related to cobalt and chromium
Audiometry (AUQ)	<ul style="list-style-type: none"> • Cycled in 27 questions from 2011-2012 Audiometry (AUQ) and moved in 2 questions from the Chemosenses questionnaire 2013-2014 (AUQ136 and AUQ138)
Chemical Senses-Taste & Smell (CSQ)	<ul style="list-style-type: none"> • Entire section cycled out
Oral Health (OHQ)	<ul style="list-style-type: none"> • Cycled out 7 questions related to prescription fluoride drops or tablets and periodontal assessment
Sleep Disorders (SLQ)	<ul style="list-style-type: none"> • Replaced 2 questions with 2 new questions to calculate data for the hours of sleep • Cycled in 3 questions from 2007-2008 Sleep Disorders questionnaire (SLQ) to obtain the symptoms of obstructive sleep apnea information

	for HP2020 objectives
Diet Behavior & Nutrition (DBQ)	<ul style="list-style-type: none"> • Modified target age for WIC questions (FSQ651 - FSQ695) from 0-11 to 0-5 years • Modified 3 questions to make the questions easier for respondents.
Weight History (WHQ)	<ul style="list-style-type: none"> • Added 3 questions to modify the OGTT protocol in the MEC to exclude additional participants who had bariatric surgery for weight loss.
Smoking (SMQ)	<ul style="list-style-type: none"> • Modified introduction to include other tobacco products. • Added 1 question related to color of cigarette pack of usual cigarettes • Added 5 questions on ever and past 30 day use of cigars, e-cigarettes, and smokeless tobacco, and use of cigarettes for respondents who have not smoked 100 cigarettes in their entire life
Occupations (OCQ)	<ul style="list-style-type: none"> • Added 1 question related to occupational protective hearing devices and 4 noise exposure questions that are part of the Audiometry examination
Prescription Drugs (RXQ)	<ul style="list-style-type: none"> • Added 10 new questions related to use of medication for anxiety and depression that were also added in the DLQ section • Modified CAPI instructions to provide more complete data on aspirin use for secondary prevention

Family Questionnaire

Component Name and ID 3 Letters)	Descriptions
Consumer Behavior (CBQ)	<ul style="list-style-type: none"> • Modified 2 questions to help respondents better understand the questions
Income (INQ)	<ul style="list-style-type: none"> • Updated the prefills with the HHS2014 poverty guidelines • Change target age group for the asset questions from low-income families to all participants • Added 1 question to assess whether a household has access to a vehicle for food shopping
Food Security (FSQ)	<ul style="list-style-type: none"> • Removed 9 questions and replaced with 27 new questions to obtain extended information in relation to WIC program and SNAP/Food stamps. The new questions will provide more detailed information in conjunction with the data from the dietary recall and other exams in the MEC.

MEC Questionnaire - CAPI

Component Name and ID (3 Letters)	Descriptions
Volatile Toxicant (VTQ)	<ul style="list-style-type: none"> • Modified 2 questions to ask more extended information about all inhaled smoke (campfires,

	fireplaces, marijuana, tobacco, etc.)
Current Health Status (HSQ)	<ul style="list-style-type: none"> • Modified 1 question about HIV test to be identical with NHIS questionnaire. • Cycled out 5 questions that were part of current health status.
Creatine Kinase (CKQ)	<ul style="list-style-type: none"> • Entire section cycled out
Reproductive Health (RHQ)	<ul style="list-style-type: none"> • Replaced 1 question with 2 new questions to simplify the exclusion of women who are categorically ineligible to receive WIC benefits • Replaced 3 questions with 6 new questions that will determine WIC participation for pregnant women and postpartum women separately. The new questions were adapted from ECLS_B.

MEC Questionnaire - ACASI

Component Name and ID (3 Letters)	Descriptions
Smoking and tobacco use (SMQ)	<ul style="list-style-type: none"> • Cycled out 3 questions related to use of nicotine replacement therapy
Sexual Behavior (SXQ)	<ul style="list-style-type: none"> • Modified response categories for 2 questions to be identical with NHIS questions

a. Food Security and Nutrition Program Participation

The 2015-16 NHANES continues to include a food security section (FSQ) that contains the 18-item U.S. Household Food Security Survey Module (US FSSM). As noted in the table above for 2015 we are modifying the questions on participation in the Supplemental Nutrition Assistance Program (SNAP and the Household and Child Special Supplemental Nutrition Program for Women, Infants and Children (WIC).

b. Dietary Supplement Use

NHANES continues to collect dietary supplement (DS) use information on all respondents during the household interview. The information collected on DS and antacid use pertains to all DSs and antacids taken in the past 30 days. This includes the name of the specific supplement, duration and frequency of use, and the amount taken. Since 2007-2008 NHANES has collected a 24 hour supplement intake recall after both of the dietary recalls.

c. Prescription Drug and Aspirin Use

NHANES continues to collect information on all prescription medications (RXQ) used by participants during the past month. The duration of drug use and reason for use are also collected. Prevention of cardiovascular disease is the most critical public health issue in the U.S. Taking low-dose aspirin regularly has been shown to significantly reduce the risk of heart attack and stroke. In addition, numerous studies have suggested that aspirin may hold promise in helping to prevent cancer. Since 2011-12, eleven questions have been asked about the prophylactic use of aspirin. Aspirin is indicated for use in patients with a prior myocardial infarction, unstable angina, or transient ischemic attack. However, currently survey participants < 40 years of ages with diagnosed cardiovascular disease are not included because the target population of the preventive aspirin questionnaires are 40 years and older. To provide more completed data on aspirin use for secondary prevention, we modified a check item at the

beginning of the preventive aspirin use questionnaires.

d. Mental Health (Depression)

NHANES continues to administer a depression screener questionnaire (DPQ) to all respondents 12 years and older at the MEC. In 2015 we are adding 6 questions from the 2015 NHIS on depression and anxiety to the household disability status questionnaire (DLQ) section of NHANES. Correspondingly, CAPI instructions added into the RXQ.033 to capture prescription medication use for anxiety or depression for those who report taking medication for anxiety or depression in the DLQ. Check items added if none of initially selected drugs is used for anxiety or depression.

e. Audiometry (hearing)

In 2015-2016, NHANES will add back questions related to hearing status, that were included in the 2011-2012 NHANES, to complement the return of the audiometry component to the survey. Two questions from the Chemosense questionnaire (CSQ) that is being cycled out in 2015-16 will be added to this section as well.

f. Weight History, Weight Self Image and Weight Related Behavior

NHANES continues to collect data for participants 8 and older on weight history and weight self-image. The information on 8-15 year olds will be used with socio-demographic and related nutrition and health information to develop programs to prevent and manage overweight among children and adolescents. The weight history questions, for participants 16 years and older, is designed to permit evaluation of height loss with aging and weight status (stable or cyclical) over time. Added 1 new question about “yo-yo” dieting, cycled out 7 questions about rarely reported behaviors and modified 1 question by adding a response category.

g. Oral Health

Seven questions will be dropped.

h. Urologic Health

Self-reported information on urinary incontinence and nocturia will continue to be collected. These data are collected during the MEC CAPI interview. NHANES will provide national estimates on the prevalence of urinary incontinence and quality of life issues for those affected.

i. Pubertal Maturation Self-assessment

The pubertal maturation self-assessment questions are administered during the MEC Audio Computer-Assisted Self-Interview (ACASI) interview, for participants 8 to 19 years old have been asked since 2011-12. These data will improve the utility of NHANES clinical, biomarker, and questionnaire data. Information on pubertal maturation status is useful to include in NHANES since the endocrine changes manifested in secondary sexual characteristics underlie many physiological changes during puberty. Sexual development correlates more closely with physical changes such as height, weight, bone density and certain biochemical markers than chronological age, thus facilitating assessment of body composition in pre-adolescence and adolescence. Furthermore, early sexual maturity has been found to closely correlate with self-

image and sexual behaviors, which are also assessed in the MEC interview.

j. Other Interview Information

The NHANES interviews include questions that are also asked in other population surveys. Typically, these questions are used as covariates in data analyses rather than to compute national prevalence estimates. Some examples in NHANES are the Demographic (DMQ), Income (INQ), Health Insurance (HIQ), Housing Characteristics (HOQ), Health Care Utilization (HCQ), and Occupation (OCQ) sections.

Additional questions are included in the survey to assess such topics as reproductive health, risk behavior, and diet behavior in the U.S. population. Brief descriptions of the major NHANES supporting interview sections are provided.

Alcohol Use: Questions on alcohol use are included for all participants 12 years and older. The questions are designed to ascertain quantity and frequency of use for quantifying alcohol intake; to identify nondrinkers, light drinkers, and former heavy drinkers; and to determine the frequency of heavy drinking occasions among current drinkers. Data on alcohol intake during the previous day will also be obtained as part of the 24-hour dietary recall.

Cigarette and Tobacco Use: The 3 questions about nicotine replacement therapy in the MEC for the participants ages 12 -17 will be discontinued. A total of 11 new questions for the participants 16 years and over are added in the household interview. Four follow-up questions will be asked of participants who have never smoked 100 cigarettes in their life to obtain additional information on age of initiation and current cigarette use. One new question on color of cigarette pack will improve identification of cigarette brand of current cigarette users, particularly for respondents who do not have a pack available at the time of the interview. Six new questions track the past and present use of cigars, e-cigarettes, and smokeless tobacco, due to an increase in prevalence.

NHANES has collaborated with the Office of Smoking and Health (OSH) since 1999. The primary objective of tobacco related content on NHANES from 1999-2010 was to measure exposure to environmental tobacco smoke. The National Center for Environmental Health (NCEH) laboratory has measured cotinine on NHANES since 1988. Many of the questionnaire items on the NHANES family, household and MEC are to assess reported exposure to tobacco products. Since 2011 NHANES has had additional laboratory measures of exposure to tobacco products on NHANES to establish reference values for these chemicals in anticipation of some or all of these being measured on the PATH survey.

For 2015 OSH began a collaboration with the National Health Interview Survey. As a result of new questions added to the NHIS ten new questions mentioned above were added to NHANES. They address these issues:

- Three questions about ever use of use of cigars, e-cigarettes and smokeless tobacco. (Note NHANES has had content related to these in past years. For 2015-16 the wording closely aligns with NHIS). For each of these three, a follow-up question is asked about the past 30 day user. (SMQ.890, SMQ.895, SMQ.900, SMQ.905, SMQ.910, SMQ.915)
- Four new questions asked of sample participants who have not smoked at least 100 cigarettes in their lifetime. (SMQ.925, SMQ.930, SMQ.935, SMQ.080)

NHANES has a few minor variations from the NHIS for these questions:

- NHANES has omitted the long introduction to each question which includes some of the product names because we have added a hand card which shows pictures of what the products look like.
- NHIS has a follow-up question that asks respondents if they now use the product “everyday, some days or not at all. By collecting the past 30 days use on NHANES the same information is available.
- NHANES does not ask a question about ever and past 30 days pipe use because of the low prevalence. However, pipe use is asked in the past 5 day use question along with use of every form of tobacco in the MEC. These questions are specifically asked to differentiate environmental exposure versus tobacco use when evaluating the laboratory results.

Reproductive Health and History: Information about women’s reproductive health is essential for evaluating their health status and the relationship of menopausal status to chronic disease. A personal private interview is conducted with females 12 years and older. Information is obtained on age at menarche, pregnancy history, history of breast feeding, history of hysterectomy and oophorectomy, menopausal status and symptoms of menopause, and use of exogenous hormones (oral contraceptives, hormone replacement therapy). In 2015-2016 we are adding 8 questions and discontinued 4 questions. The two new questions will simplify the exclusion of women who are categorically ineligible to receive WIC benefit and the 6 new questions will determine WIC participation for pregnant women and postpartum women separately. The new questions were adapted from ECLS_B.

Sexual Behavior: The information on sexual behavior is key to reducing the risk of sexually transmitted diseases (STDs). Participants 14 -59 years are asked about age of first intercourse, number of sexual partners, use of condoms, and history of sexually-transmitted diseases. The questions on sexual behavior are included to provide for targeting risk reduction efforts; assessing the results of such efforts; and improving current understanding of the epidemiology of STDs. In 2015-2016 questionnaire, we modified answer categories of one sexual identity question (SXQ294: female and SXQ292: male) in order to be consistent with answer categories used in other NCHS surveys (NHIS).

Drug Use: Questions on drug use are included for participants 14-59 years. The questions focus on lifetime use of street drugs or recreational drugs and the intravenous use of these drugs. Additional questions on age of initiation of drug injection, duration of injection drug use, and lifetime history of drug treatment are included in this section. The use of drugs has been demonstrated to be a risk factor for sexually transmitted diseases. Injection drug use is also a risk for blood borne pathogens such as HIV, HBV and HCV. Information on drug use is necessary along with sexual behavior questions to develop a profile of risk-taking behavior. Participants ages 60-69 will be asked a selected subset of these questions.

Responding to Emerging Public Health Issues, New Technology and Future Survey Options

One objective of the continuous NHANES is to provide a mechanism to respond to emerging and re-emerging public health topics. The content of the survey is modified biannually to accomplish this objective. Survey modifications may include removing or “cycling out” survey content that has been in the survey for multiple years, modifying existing survey content to include new target age groups, modified data collection methods, the use of updated technology, and the addition of new interview, laboratory, and examination components and topics. The NHANES Program utilizes a public proposal solicitation process to develop recommendations for survey content. The process and proposal guidelines are posted on the NHANES website (http://www.cdc.gov/nchs/about/major/nhanes/research_proposal_guidelines.htm). NCHS disseminates this information to survey collaborators, federal agencies, and NHANES data users.

The Division of Health and Nutrition Examination Surveys (DHANES) anticipates that new technology will be adopted during future data collection activities. NCHS staff design, plan, implement and evaluate numerous methodology projects to evaluate new technology proposed for use in NHANES. For example, new questionnaire items or sections and examination component protocols are often pre-tested in-house and in the field prior to full survey implementation. This process may include cognitive testing of questions as well as pilot testing of content in the actual NHANES environment. Past experience has shown that one to three years of preparatory work may be required to fully test and prepare a new NHANES examination component for the survey. New equipment must be installed, calibrated, and tested; software must be installed and tested; database variables and data processing procedures must be developed and documented; data security provisions must be developed, tested, and approved; and training manuals, staff training, and quality control procedures must be developed.

In certain cases, additional testing using non-NHANES respondents may be necessary. This could occur, for example, when the NHANES is developing a method to be used in the survey that can be tested or calibrated outside the NHANES survey setting. For example prior to pilot testing an NHANES 24 hour urine collection within the survey a calibration study was done with remunerated volunteers.

Pilot Tests for the 2015-16 NHANES

Only one pilot test was conducted for potential inclusion in the 2015-16 NHANES. That was a pilot test on collecting a urine specimen during the MEC examination on children ages 3-5.

The pilot was successful. Ninety-eight percent of the 3-5 year olds provided a urine sample and 81% were able to provide our target of 60 ml or more of specimen. One-hundred and twenty-one children had some urine for testing. Their results were reviewed to determine if their results were above the level of detection and similar to 6-8 year olds results from the 2011-12 NHANES. The comparison was not statistical but qualitative. Results were from these classes of chemicals: heavy metals and iodine; phenols and phthalate metabolites; phytoestrogens; polycyclic aromatic hydrocarbon metabolites; tobacco biomarkers (including NNAL and volatile nitrosamines); and volatile organic compounds. In 2015-16 we plan to include urine specimens for children ages 3-5 in the protocol. In contrast to ages 6 and older where only a 1/3 sample

are tested for the environmental chemicals all children 3-5 will be sampled because of the small size of this age domain.

Methodological Studies to be conducted during NHANES 2015-16

NHANES expects to conduct several methodological studies during 2015-16. Possibilities include tests such as:

- Ankle Brachial Pressure Index.
- Peripheral neuropathy.
- Fundus photography.
- Digital photographs of dietary supplement and/or prescription medication container labels.
- Collection of an unsmoked cigarette from smokers for laboratory analysis.
- Ambulatory blood pressure monitoring
- Waist circumference using multiple methods
- Pilot test the procedures to be used to recontact participants at 6, 12, 18 and 24 months to assess persistence, disappearance and acquisition of oral HPV infection. The testing would be of the mailing and recontact procedures.

For these projects and any currently unforeseen methodological studies, a non-substantive change package would be submitted to OMB before undertaking the study.

Pilot Tests to be conducted in 2015-16 for the 2017-18 NHANES

The survey expects to continue conducting pilot studies for future cycles of continuous NHANES. During 2015-2016, pilot studies will be conducted to prepare for implementation during NHANES 2017-2018. A non-substantive change package would be submitted to OMB before undertaking any pilot study.

Special Studies and Additional Health and Nutrition Examination Studies

This request permits NCHS the option to plan and test additional Health and Nutrition Examination components outside the current sample. Such a project would directly relate to the future or current content of the NHANES.

CDC is including burden hours to accommodate such special studies (Attachment 10) involving up to 2,331 participants (Section A12, Table 1, line 2), however, CDC understands that such special studies would require submission of a full revision to OMB for clearance.

Nonresponse Investigation

Nonresponse investigations under DHHS task order contracts or other contract mechanisms may be necessary should nonresponse rates make that advisable. Details of any such investigations that involve public participation will be described under a non-substantive change package using burden from pilot of methodological studies.

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 April 11, 2014, volume 79, number 70, pp. 20204 - 20205. 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

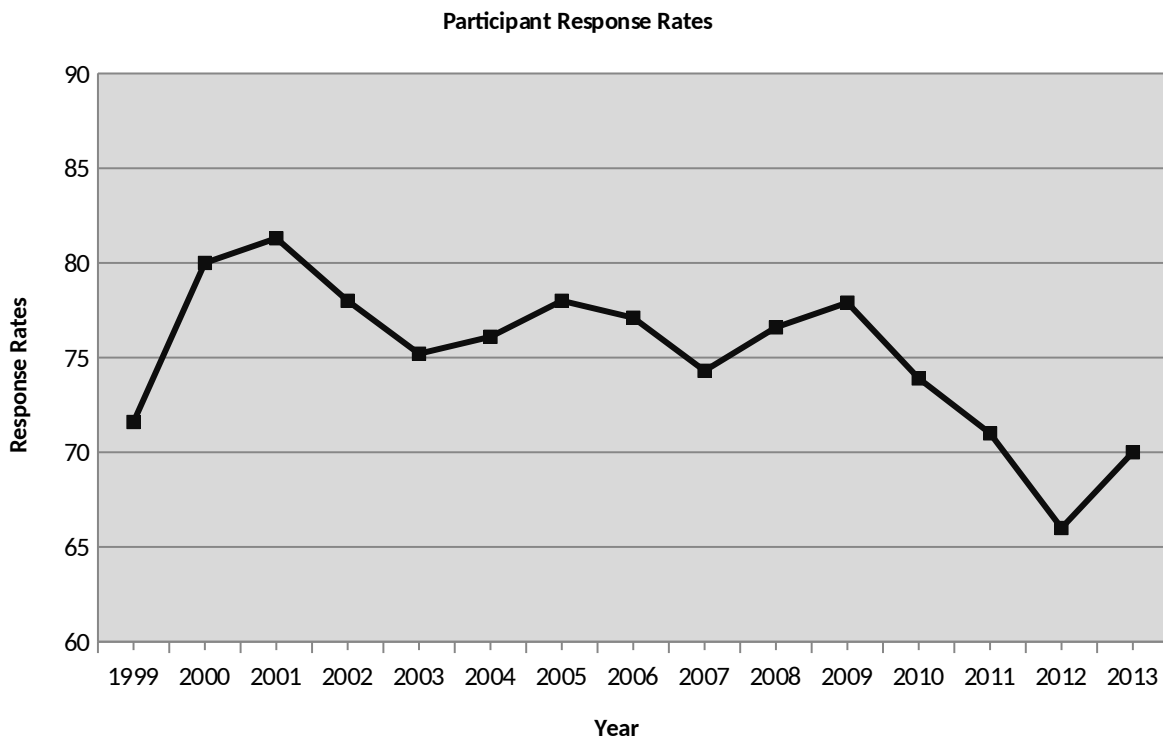
To maximize response rates for the examination, NHANES participants have been remunerated for their examination participation since the 1970s. Remuneration began after a study was conducted to test the effect of remunerating sample persons who participated in NHANES I.

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.

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. Assurance of Confidentiality Provided to Respondents

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.

10.1 Privacy Impact Assessment Information

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.

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. Justification for Sensitive Questions

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 on 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].)

Up to 2,500 additional persons (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 7,500 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
1. Individuals in households	NHANES Questionnaire	14,410	1	2.5	36,025
2. Individuals in households	Special Studies	2,500	1	3	7,500
Total					43,525

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 planning, data analysis and overhead	\$6,000,000
NCHS printing, travel, supplies, etc. for NHANES staff	\$200,000
Total	\$41,200,000

15. Explanation for Program Changes or Adjustments

The requested burden is 43,525. The burden for the previous cycle of NHANES was 46,028. This change in burden is due to fewer screeners being done in 2015-2016.

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 survey begins
• 2015-2016 data collection	Three years after data collection begins
• First public release of data	Six months after data collection ends
• First publication of summary statistics	Six months after data collection ends

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.