

Supporting Statement A for Request for Clearance

National Health and Nutrition Examination Survey

OMB No. 0920-0950

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SECTION A TABLE OF CONTENTS

SECTIONS	PAGES
A. Justification.....	5
1. Circumstances Making the Collection of Information Necessary.....	5
2. Purpose and Use of the Information Collection.....	5
3. Use of Information Technology and Burden Reduction.....	16
4. Efforts to Identify Duplication and Use of Similar Information.....	16
5. Impact on Small Businesses or Other Small Entities.....	17
6. Consequences of Collecting the Information Less Frequently	17
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	17
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....	17
9. Explanation of Any Payment or Gift to Respondents.....	18
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.....	19
11. Institutional Review Board (IRB) and Justification for Sensitive Questions.....	23
12. Estimates of Annualized Burden Hours and Costs.....	26
13. Estimate of Other Total Annual Cost Burden to Respondents And Record Keepers.....	28
14. Annualized Cost to the Federal Government.....	28
15. Explanation for Program Changes or Adjustments.....	29
16. Plans for Tabulation and Publication and Project Time Schedule.....	29
17. Reason(S) Display of OMB Expiration Date is Inappropriate.....	29
18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	29

Supporting Statement A

National Center for Health Statistics (NCHS) National Health and Nutrition Examination Survey (NHANES)

- 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 12/31/2017). 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 2017-18,
- collect follow-up data and conduct activities related to data collection/processing through 2019,
- conduct developmental studies to support data collection for 2019 and beyond,
- conduct non-response studies as needed.

Brief summary of planned changes for the 2017-18 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 2017-18.

Adding/modifying in 2017-18

- A liver ultrasound elastography (LUE) exam (ages 12+)
- A set of alcohol and liver-related questions, and a hip measurement will also be added to complement the liver exam (ages 12+)
- The age range for liver-related blood test (serum ferritin) already collected in NHANES is

being expanded from female participants 12-49 to all participants 12 years and older (The existing collection of serum ferritin in children 1-5 years will continue)

- Cycling back into the Dual X-ray Absorptiometry (DXA) exam is the bone density for hip and spine (ages 50+)
- The osteoporosis questionnaire will also cycle back into NHANES to complement the changes to the DXA exam. These questions will be asked of those 50+ In addition, the age range for the existing DXA total body scan will be changed from 6-59 years to 8-69 years
- Modifying the audiometry (hearing) age groups to participants ages 6-19 and 70+ years.
- a blood pressure methodology study (ages 6+)
- 12 Tobacco biomarkers in urine (ages 3+)
- metals in whole blood are changing from a one-half sample to a full sample (ages 1+)
- two metals in urine (ages 3+)
- three phthalates in urine (ages 3+)
- Polycyclic Aromatic Hydrocarbons (PAHs) are being discontinued in the smoker oversample subgroup, however testing will continue in a 1/3 subsample of general NHANES participants
- one insect repellent in urine (ages 3+)
- one Volatile organic compound (VOC) metabolite in urine (ages 3+)
- nine urinary flame retardants in urine (ages 3+)
- Congenital Cytomegalovirus (CMV) in sera (ages 1-5)
- Modifying the target age group for serum ferritin to all participants ages 1-5 and 12+, and adding an additional frozen serum iron to all participants 12+
- Unsaturated Iron Binding Capacity (UIBC)/Total Iron Binding Capacity (TIBC) in serum (ages 12+)
- Vitamin C in serum (ages 6+)
- Vitamins A, E, and carotenoids in serum (ages 6+)
- Cycling back in the Flexible Consumer Behavior Survey (FCBS) phone follow-up questionnaire (ages 1+)
- Expanding the use of electronic consent to include MEC exam consent forms (consent, assent, and future research) and authorization for transportation forms
- Adding a test in urine for Mycoplasma genitalium (ages 14-59)

Cycling Out of NHANES 2017-18

- pubertal maturation
- Oral Glucose Tolerance Test (OGTT)
- three metals in serum
- three hormones and binding proteins
- oral HPV collection
- Sagittal Abdominal Diameter (SAD)
- Dental fluorosis assessment and dental fluorosis imaging (DFI)
- Plasma, urine, and water fluoride
- Apo B analysis

A summary of additional changes to the questionnaire is provided in Attachment 3a.

Requests for continued permission to conduct developmental studies (such as pilot, feasibility, methodological and other developmental testing) for future NHANES will be submitted through non-substantive change requests. Special projects, including activities involving remunerated volunteers who are non NHANES participants, would be submitted for approval using a non-substantive change request or full revision, as appropriate. In the future, NHANES, plans to

submit a Generic clearance request to conduct projects conducted among non NHANES participants.

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 personal interviews, the examination (including follow-up activities), and laboratory assessments. The purposes and uses of the survey’s content are detailed below.

The NHANES Interviews

Questionnaire data are collected as stand-alone components or to complement one or more

examination or laboratory components. Questionnaires in NHANES are asked: in participants' home via interviewer-administered computer-assisted personal interviewing (CAPI); in the MEC via interviewer-administered CAPI or audio computer-assisted self-interviews (ACASI); and over the phone for follow-up interviews via interviewer-administered CAPI. The NHANES interview consists of seven major components:

1. Household Screener Questionnaire (determines eligibility)
2. Household Family Relationship Questionnaire
3. Household Sample Participant Questionnaire
4. Household Family/Household Questionnaire
5. Mobile Examination Center (MEC) Questionnaire
6. Mobile Examination Center (MEC) Post Dietary Recall Questionnaire
7. Telephone Post Dietary Recall Questionnaire

In 2017-18, two new NHANES questionnaire sections will be added, one section will be dropped and 21 sections will be modified. Thirty-one sections of the NHANES questionnaire will not be changed. The two new sections and one dropped section are summarized below.

New Sections:

Osteoporosis (OSQ) will be added back into to the Household Sample Participant Questionnaire. It consists of 26 questions previously asked in NHANES 2001-2010 and 2013-2014 cycles. The osteoporosis questionnaire is being added back into NHANES to complement the changes to the DXA exam.

The Flexible Consumer Behavior Survey (FCBS) will be added back into the Telephone Post Dietary Recall Questionnaire (Phone-Post Dietary). It has been revised (from the FCBS used in past NHANES) to help assess the impact of both FDA's upcoming restaurant menu labeling regulations and their Nutrition Facts Label changes.

Dropped Section:

The Pubertal Maturation (PMQ) section will be dropped from the MEC ACASI.

Attachment 3a provides a description of all questionnaire changes (including modifications) and the rationales for them. The complete set of 2017-18 questionnaires (1-7 as described above) and hand cards are in Attachment 3b. This attachment begins with a table of contents that lists each questionnaire section by component name and corresponding 3 letter component abbreviation. (For NHANES 2015-16 questionnaires and hand cards see Attachments 3c and 3d respectively.)

Below are brief descriptions of select questionnaire sections.

Food Security and Nutrition Program Participation (unchanged)

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).

Dietary Supplement Use (modified)

NHANES continues to collect dietary supplement (DS) and antacid 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.

Prescription Drug and Aspirin Use (unchanged)

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.

Mental Health (Depression) (unchanged)

NHANES continues to administer a depression screener questionnaire (DPQ) to all respondents 12 years and older at the MEC.

Audiometry (hearing) (modified)

NHANES continues to administer questions related to hearing status. The target age groups for NHANES 2017-18 have been modified to include participants ages 6-19 and 70+.

Weight History, Weight Self Image and Weight Related Behavior (unchanged)

NHANES continues to collect data from participants 8 and older on weight history and weight self-image. The information from 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, from participants 16 years and older, is designed to permit evaluation of height loss with aging and weight status (stable or cyclical) over time.

Oral Health (modified)

NHANES continues to collect information on oral health for participants ages 1 and older (resources permitting).

Urologic Health (unchanged)

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.

Pubertal Maturation Self-assessment (dropped)

The pubertal maturation self-assessment is being dropped in 2017-18.

Flexible Consumer Behavior Survey (FCBS) (new)

The Flexible Consumer Behavior Survey (FCBS) will be added back into the Telephone Post Dietary Recall Questionnaire (Phone-Post Dietary) in 2017-18. Because of changes to restaurant menu labeling and the Nutrition Facts label (NFL), as well as the interest in sodium reduction efforts, FDA and the Economic Research Service (ERS) jointly proposed minor revisions to the Flexible Consumer Behavior Survey (FCBS) component used in past (NHANES). The goal of the revised FCBS is to collect data that will allow ERS, FDA, and other researchers to examine 1) consumers' use of nutrition information at restaurants before and after the new rule is implemented, 2) consumers' use of the NFL before and after the NFL's redesign, and 3) consumers' sodium reduction practices and health care providers' role in the

practice.

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 select 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 determine the frequency of heavy drinking occasions among current drinkers and among adults to ascertain quantity and frequency of use for quantifying alcohol intake; to identify nondrinkers, light drinkers, and former heavy drinkers. Data on alcohol intake during the previous day will also be obtained as part of the 24-hour dietary recall. The alcohol questions are being modified to complement the new liver ultrasound elastography (LUE) exam.

Cigarette and Tobacco Use: A primary objective of tobacco-related content in NHANES since 1999 has been to measure exposure to environmental tobacco smoke. The National Center for Environmental Health (NCEH) laboratory has measured cotinine on NHANES since 1988. And since 2011, NHANES has had additional laboratory measures of exposure to tobacco constituents in order to establish reference values for these chemicals in anticipation of some (or all of these) being measured on the Population Assessment of Tobacco and Health (PATH) Study.

To complement the NCEH laboratory tobacco component, and to provide co-variates for analyses where tobacco use is an important risk factor, NHANES continues to ask questions about cigarette and tobacco use, including the use of cigars, e-cigarettes, smokeless tobacco. NHANES has collaborated with the CDC Office on Smoking and Health (OSH) since 1999. Questions on tobacco use and exposure are asked of those 18 years and older, and about tobacco exposure for participants 0-11 years (by proxy) in the Household Interview. In the MEC Interview, participants 12-17 answer questions about tobacco use and exposure for themselves. Adults 18 years and older are asked about past 5 day use of all forms of tobacco

In 2015 OSH began a collaboration with the National Health Interview Survey (NHIS). As a result, new questions were added to the NHIS. Of these questions, ten were added to NHANES 2015-16 and six will be continued in 2017-18. 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 forward, the wording closely aligns with NHIS). For each of these three, a follow-up question is asked about the past 30 day user.
- The four questions asked of sample participants who have not smoked at least 100 cigarettes in their lifetime. (SMQ.925, SMQ.930, SMQ935, and SMQ.080) will be discontinued in 2017-18 because they are no longer included in NHIS.
- In 2017-18, NHANES will include several questions about e-cigarette exposure. These questions will be asked to participants of all ages (0-11 years by proxy).

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 interview. 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). Since 2015-2016 we have included questions that simplify the exclusion of women who are categorically ineligible to receive WIC benefits and questions that determine WIC participation for pregnant women and postpartum women separately. These 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. Since 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.

NHANES Examination

NHANES Examination changes for 2017-18 include:

- Adding a liver elastography (ultrasound) exam for participants 12 years and older.
- Adding a set of alcohol and liver-related questions, liver-related blood tests, and a hip measurement to complement the liver exam.
- Cycling bone density for hip and spine back into the Dual X-ray Absorptiometry (DXA) exam for (ages 50+).
- Cycling back in the osteoporosis questionnaire (ages 50+) to complement the changes
- Adding a blood pressure methodology study (ages 6+)
- Modifying the age range for the existing DXA total body scan from 6-59 years to 8-69 years.
- Dropping the Sagittal Abdominal Diameter (SAD) from the body measures (anthropometry) exam.

See Attachment 3a for a summary of NHANES 2017-18 questionnaire changes (including MEC interviews). See Attachments 3b 2017-18 data collection forms (including hand cards and exam forms). (See Attachments 3c and 3d for data collection forms (including exam forms) and Hand Cards used in NHANES 2015-2016.)

Below are brief descriptions of select examination sections.

Chronic Conditions (modified)

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, and Triglyceride.

Diabetes Mellitus (DM) (modified) NHANES continues to monitor DM via fasting insulin and measurement of glycohemoglobin (HbA1c). The household interview will include questions about diabetes awareness and treatment. The Oral Glucose Tolerance Test (OGGT) is being dropped in 2017-18.

Obesity (modified) NHANES will continue to collect body measures of height, weight, circumferences and skinfold thicknesses (anthropometry). Sagittal Abdominal Diameter (SAD) will be dropped from body measures. Body composition (lean and fat mass), by dual-energy X-ray absorptiometry (DXA) will continue.

Chronic Liver Disease (CLD) (new)

NHANES is adding a - liver ultrasound elastography (LUE) exam for participants 12 years and older. The purpose of this exam is to measure liver fatness (hepatic steatosis) and liver stiffness (an indicator of liver fibrosis) by gender and other demographic characteristics, such as race/ethnicity. A set of alcohol and liver-related questions, liver-related blood tests, and a hip measurement will also be added to complement the liver exam. These tests include C-reactive protein, ferritin, Unsaturated Iron Binding Capacity (UIBC) and Iron. Information for this component will be used to investigate the public health burden of components of CLD including Non-Alcoholic Fatty Liver Disease (NAFLD). See Attachment 4 for a report of the pilot test for the liver elastography equipment to be used.

Dietary Assessment (unchanged)

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.

Osteoporosis, (modified)

Cycling back into the Dual X-ray Absorptiometry (DXA) exam for (ages 50+) is the bone density for hip and spine. The scans will provide estimates of the prevalence of low bone mass and osteoporosis. The osteoporosis questionnaire will also cycle back into NHANES to complement the changes to the DXA exam. These questions will be asked of those 50+. In addition, the age range for the existing DXA total body scan will be changed from 6-59 years to 8-69 years

Oral Health (modified)

The target age group for the Oral Health component continues to be participants ages 1 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, and dental sealants. The rinsed specimen to test for oral Human Papilloma Virus (HPV) infection, the dental fluorosis assessment and dental fluorosis imaging (DFI) are being dropped from the survey in 2017-18.

Audiometry (modified)

The target age group for the audiometry component is being changed to participants ages 6-19 and 70+. (In NHANES 2015-16 the target was participants 20-69 years old.) 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.

HPV swabs in males and females (unchanged)

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 2017-18 include:

Adding:

- 12 tobacco biomarkers in urine (ages 3+)
- two metals in urine (ages 3+)
- three phthalates in urine (ages 3+)
- one insect repellent in urine (ages 3+)
- one Volatile Organic Compound (VOC) metabolite in urine (ages 3+)
- nine urinary flame retardants in urine (ages 3+)
- Congenital Cytomegalovirus (CMV) in sera (ages 1-5)
- Unsaturated Iron Binding Capacity (UIBC)/Total Iron Binding Capacity (TIBC) in serum (ages 12+)
- one additional frozen serum iron is being added to participants 12+ (liver-related blood tests)
- Vitamin C in serum (ages 6+)

- Vitamins A (retinol), E, and carotenoids in serum (ages 6+)
- A test in urine for Mycoplasma genitalium (ages 14-59)

Modifying:

- the target age group for serum ferritin to include participants ages 1-5 and 12+ years
- metals in whole blood are changing from a one-half sample to a full sample (ages 1+)
- Polycyclic Aromatic Hydrocarbons (PAHs) are being discontinued in the smoker oversample subgroup, however testing will continue in a 1/3 subsample of general NHANES participants

Dropped:

- Oral Glucose Tolerance Test (OGTT)
- three metals in serum
- three hormones and binding proteins
- oral HPV collection
- Apo B analysis
- Plasma, urine, and water fluoride

See Attachment 5a for a detailed list of planned laboratory tests conducted in NHANES 2017-18. See Attachment 5b for a detailed list of laboratory tests for NHANES 2015-2016.

Below are brief descriptions of select laboratory assessments.

Urine Assessments

Urine Flow Rate (unchanged)

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 3 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.

Environmental Chemical Exposures (modified)

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 450 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, 2015 includes 265 chemicals of which 65 are new and 139 have updated data since the Updated Tables, August 2014.

In general, within classes of chemicals, analytes new in 2017-18 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 5a). 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 2017-18**):

- Tobacco biomarkers (See changes below)
- Metals (See changes below)
- Phthalates and phthalate alternatives (See change below)
- Personal care and consumer product chemicals and metabolites
- Polycyclic Aromatic Hydrocarbons (PAHs) (See changes below)
- Non-persistent pesticides (organophosphate insecticides, pyrethroid pesticides)
- Other pesticides/insect repellents (See change below)
- Perfluorinated compounds
- Environmental phenols and organochlorine pesticides
- Polychlorinated and polybrominated dibenzo-p-dioxins and dibenzofurans
- Polychlorinated biphenyls (PCBs)
- Polybrominated diphenyl ether
- Volatile organic compounds (See changes below)
- Flame retardants (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

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 (See change below)
- Aldehydes
- Aromatic amines (See change below)
- Heterocyclic amines (See changes below)

Tobacco-specific nitrosamines (TSNAs)

- One cotinine and nicotine analog (4-Hydroxy-4-(3-pyridyl) Butanoic acid) is being added to the protocol
- One aromatic amine (1-Aminonaphthalene) is being added to the protocol
- 10 heterocyclic amines are cycling back in from 2013-2014: 3-Amino-1,4-dimethyl-5H-pyrido[4,3-b]indole (Trp-P-1); 2-Amino-3-methyl-9H-pyrido[2,3-b]indole (MeA- α -C); 2-Amino-1-methyl-6-phenylimidazo[4,5-b]pyridine (Ph1P); 2-Amino-9H-pyrido[2,3-b]indole (A- α -C); 2-Amino-3-methylimidazo[4,5-f]quinoline (IQ); 2-Amino-6-methyldipyrido[1,2-a:3',2'-d]imidazole (Glu-P1); 2-Aminodipyrido[1,2-a:3',2'-d]imidazole (GLU-P2); Harman; 1-Methyl-3-amino-5H-pyrido[4,3-b]indole (Trp-P-2); and Norharman

Metals

Numerous metals are measured in the urine and whole blood of NHANES participants. Measurements of metals in whole blood are expanding from a one-half sample to a full sample for participants' ages 12+ (participants ages 1-11 are already a full sample). The measurement of metals in serum are being discontinued, and two additional metals in urine (chromium and nickel) are being added to the 2017-18 cycle.

Phthalates and Phthalate Alternatives

Three phthalates are being added to the 2017-18 protocol: Mono-hydroxyisodecyl phthalate (MHDP); Mono-oxoisodecyl phthalate (MODP); and Mono-oxoisobutyl phthalate (MONP).

Polycyclic Aromatic Hydrocarbons (PAHs)

Polycyclic Aromatic Hydrocarbons (PAHs) are being discontinued in the smoker oversample subgroup, however testing will continue in a 1/3 subsample of general NHANES participants.

Other Pesticides/Insect Repellents

One insect repellent compound (3-(Ethylcarbamoyl) Benzoic Acid) is being added to the 2017-18 protocol.

Volatile organic compounds (VOC) (blood and urine)

One volatile organic compound (N-Acetyl-S(((4-[Methylsulfinyl] butyl)amino)thioxomethyl)-L-cysteine (SUMA)) is being added to the 2017-18 profile.

Flame Retardants

Nine urinary flame retardants are being added to the 2017-18 protocol: Bis(1-chloro-2-propyl) phosphate (BCPP), Bis(2-chloroethyl) phosphate (BCEtP), Bis(1,3-dichloro-2-propyl) phosphate (BDCPP), Dibenzyl phosphate (DBzP), Dibutyl phosphate (DBuP), Di-p-cresylphosphate (DpCP), Di-o-cresylphosphate (DoCP), Diphenyl phosphate (DPhP), and 2,3,4,5-Tetrabromobenzoic acid (TBBA).

Infectious Disease and Immunization Status Assessments (modified)

The HPV Oral rinse collected in the MEC is being dropped in 2017-18. The vaginal swab in females ages 14-59 and penile swab in males ages 14-59 for human papilloma virus (HPV), and urine trichomonas and chlamydia in participants 14-59 will continue.

Laboratory tests for the following infectious diseases include the following categories (**unless noted there are no changes in the biomarkers within a category for 2017-18**):

Trichomonas vaginalis
Chlamydia trachomatis
Hepatitis profile
Herpes simplex 1 and 2
Human Immunodeficiency Virus (HIV)
Human Papilloma Virus (HPV) (vaginal and penile swabs)
Cytomegalovirus (CMV) (IgG and IgM antibodies) (See changes below)

Congenital Cytomegalovirus (CMV)

CMV is cycling back in from 2011-12 in participants ages 1-5.

Mycoplasma Genitalium (new)

A test in urine for *Mycoplasma genitalium* (ages 14-59) is being added. *Mycoplasma genitalium*, first identified in the 1980s, is an emerging sexually transmitted pathogen in men and women. Little is known about its population prevalence and trends in its antibiotic resistance. This test is being added to NHANES to estimate a point prevalence of *Mycoplasma genitalium* in the United States and to assess levels of antibiotic resistance in *Mycoplasma genitalium* positive specimens.

Nutritional Biochemistries, Hematologies and other Nutrition-Related Analytes

Laboratory tests for the following nutrition biomarkers include the following categories (**unless noted there are no changes in the biomarkers within a category for 2017-18**):

- Complete blood counts
- Serum and red blood cell folate
- Standard biochemical profile
- Serum lipids
- Urinary iodine
- Serum ferritin (See below for changes)
- Transferrin receptor
- C-Reactive Protein (CRP)
- Vitamins A, C, E and Carotenoids (See below for changes)
- Vitamin D

The target age group for serum ferritin is being changed from female participants ages 12-49 to all participants ages 12+. The survey will continue to collect serum ferritin in all participants ages 1-5 years. The current target age for folate will continue to be 1+ years (subject to the availability of funds). If necessary, however, the target group could be reduced.

Vitamins A, C, and E are cycling back in from 2005-06; as well as 11 Carotenoids: Retinyl palmitate, Retinyl stearate, gamma-Tocopherol, alpha-carotene, trans-beta-Carotene, cis-beta-Carotene, alpha-Cryptoxanthin, beta-Cryptoxanthin, Lutein/zeaxanthin, trans-Lycopene, and total lycopene. *alpha*-Carotene is a new biochemical compound that has never been tested in NHANES.

Plasma, urine, and water fluoride are being discontinued.

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.

Other Laboratory

Laboratory tests for the following biomarkers remain unchanged from 2017-18:

- Hormones and binding proteins (See changes below)
- Standard biochemical profile (kidney, liver function)
- Unsaturated Iron-Binding Capacity (UIBC) and Serum Iron (See changes below)
- Urinary Fluoride

Hormones and Binding Proteins

Measurements for serum total testosterone levels, serum estradiol, and serum sex hormone binding globulin are being dropped in the 2017-18 cycle.

Unsaturated Iron-Binding Capacity (UIBC) and Serum Iron

UIBC in frozen serum is cycling back in from 2005-2006. An additional frozen serum iron is being added to accompany the UIBC measurement in the 2017-18 protocol.

3. Use of Improved 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 agencies consulted are listed in Attachment 6 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 5 CFR 1320.5

This data collection fully complies with regulation 5 CFR 1320.5.

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 May 23, 2016, volume 81, number 99, pp. 32333 - 32355. One comment was received. See Attachment 2a for a copy of the notice. See Attachment 2b for a copy of the comment and the corresponding agency response.

b. Outside Consultation

The content of NHANES is developed with input from numerous DHHS agencies (including NIH, FDA, and CDC), several USDA entities (Agricultural Research Service (ARS), Economic Research Service (ERS), and Food and Nutrition Service (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 (ASPE) 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 2017-18 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 16 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 Payment or Gift to Respondents

To maximize response rates for the examination, NHANES participants have been remunerated for their examination participation since the 1970s. The response rates for participants examined for 2014 and 2015 were 65% and 63% respectively. A graph of NHANES examination response rates from 1999-2015 as well as a brief history of NHANES remuneration are found in Attachment 7. Below are the 2017-18 NHANES remuneration rates. They are the same as those used in 2016.

Examination incentive

Subgroup	2017-18 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
FCBS Phone Follow-Up	\$15

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 2007–2018		
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 2017-18 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 July 20, 2016.

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."

Also NCHS makes the following Confidentiality Pledge:

We take your privacy very seriously. All information that relates to or describes identifiable characteristics of individuals, a practice or an establishment will be used only for statistical purposes. NCHS staff, contractors and agents will not disclose or release responses in identifiable form without the consent of the individual or establishment in accordance with section 308 (d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA), Title 5 of Public Law 107-347). In accordance with CIPSEA every NCHS employee, contractor and agent have taken an oath and is subject to a jail term of up to five years, a fine of up to \$250,0000, or both if he or she willfully discloses ANY identifiable information about you. In addition, NCHS complies with the Cybersecurity Enhancement Act of 2015. This law requires the Federal government to protect its information by using computer security programs to identify cybersecurity risks against federal computer networks.

Consequently, all information collected in NHANES will be kept confidential, with an exception for suspected child abuse and requirements of the Cybersecurity Act of 2015.

Overview of the Data Collection Process

For the 2017-18 a contractor will carry out the NHANES 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:

Advance Letter (Attachment 8)
 Household Screener Questionnaire (Attachments 3b),
 Household Relationship Questionnaire (Attachment 3b)
 Household/Family Questionnaire (Attachment 3b)
 Household Sample Person Questionnaire (Attachment 3b)
 MEC Data Collection Forms (Attachment 3b)
 Interview Informed Consent (Attachment 9a)
 Examination informed Consent (Attachment 9a)
 Stored Specimen Consent (Attachment 9a)
 Consent Brochure (Attachment 9b)
 Assent Brochure (Attachment 9c)
 Consents FAQ (Attachment 9d)

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

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
- Name of mother
- Name of father
- Parent's relationship to child
- Child's date of birth
- Child's sex
- Mailing Address
- Phone Numbers
- E-mail Address
- 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 8) 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 (Attachments 9a, 9b and 9c).

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 10).

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 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. Providing this information is voluntary and is collected under the authority of Section 306 of the Public Health Service Act and the Confidential Information Protection and Statistical Efficiency Act. There will be no effect on {your/his/her} benefits if you do not provide it.”

“What is {your/SP's} Social Security Number?”

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.

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}. Providing the Health Insurance Claim Number is voluntary and collected under the authority of the Public Health Service Act and the Confidential Information Protection and Statistical Efficiency Act. Whether the number is given or not, there will be no effect on {your/his/her} benefits. This number will be held confidential. [The Public Health Service Act is Title 42, United States Code, Section 242K; Confidential Information Protection and Statistical Efficiency Act is Public Law No: 107-347.]

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 10). 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. 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.

- vii. 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. 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 3b). 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 [attachments 9a, 9b and 9c].)

The Blood Pressure Methodology Study Phase 1 (Attachments 12a and 12b) is budgeted for 30 minutes. The maximum number of respondents would be 1,404 and the maximum burden 702 hours.

The Blood Pressure Methodology Study Phase 2 (Attachments 12c and 12d) is budgeted for 30 minutes. The maximum number of respondents would be 2,000 and the maximum burden 1000 hours.

The Flexible Consumer Behavior Survey Phone Follow-Up (Attachments 13a and 13b) is budgeted for 20 minutes. The maximum number of respondents would be 5,000 and the maximum burden 1,667 hours.

Up to 3,500 additional persons (including non-NHANES respondents) might participate in Developmental projects (such as pilot tests or methodological studies) or Special Studies, if budgeted. The average burden for these respondents is 3 hours (Attachment 14). The estimated total burden for one year for special studies is 10,500 hours.

Up to 1,200 additional persons (including non-NHANES respondents) might participate in Wearable Device projects (such as test/studies involving ambulatory blood pressure monitors or physical activity monitors, etc.). Participants may be asked to wear such devices for several hours or over a period of days. The average burden for these

respondents is 25 hours (Attachment 15) the estimated total burden for one year for Wearable Device projects is 30,000 hours.

TABLE 1 – ANNUALIZED BURDEN HOURS

Type of Respondent	Form Name	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	Blood Pressure Methodology Study Phase 1	1,404	1	30/60	702
Individuals in households	Blood Pressure Methodology Study Phase 2	2000	1	30/60	1000
Individuals in households	Flexible Consumer Behavior Survey Phone Follow-Up	5,000	1	20/60	1,667
Individuals in households	Developmental Projects & Special Studies	3,500	1	3	10,500
Individuals in households	Wearable Device Projects	1,200	1	25	30,000
Total					79,894

b. Cost to Respondents

The hourly wage rate of \$23.23 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. (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.)

TABLE 2 – Cost to Respondents

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Individuals in households	NHANES Questionnaire	36,025	\$23.23	\$836,861

Individuals in households	Blood Pressure Methodology Study Phase 1	702	\$23.23	\$16,307
Individuals in households	Blood Pressure Methodology Study Phase 2	1000	\$23.23	\$23,230
Individuals in households	Flexible Consumer Behavior Survey Phone Follow-Up	1,667	\$23.23	\$38,724
Individuals in households	Developmental Studies & Special Projects	10,500	\$23.23	\$243,915
Individuals in households	Wearable Device Projects	30,000	\$23.23	\$696,900
Total		79,894	\$23.23	\$1,855,937

13. Estimate of Other Total Annual Cost Burden to Respondents and 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 Office of Financial Resources. A proportion of these costs are paid by funds transferred to the CDC budget from collaborating agencies. It is estimated that about 5 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	\$40,000,000
NCHS staff costs for survey planning, data analysis and	\$6,000,000

overhead	
NCHS printing, travel, supplies, etc. for NHANES staff	\$200,000
Total	\$46,200,000

15. Explanation for Program Changes or Adjustments

The new requested burden as a result of this submission is 79,894 hours, an increase of 32,969 hours. While the burden hours for the questionnaire and special studies lines remain unchanged from the currently approved package, the hours for a completed waist circumference study have been deleted. Meanwhile, this submission captures new lines of burden for two phases of a Blood Pressure Methodological Study, a Flexible Consumer Behavior Survey Phone Follow-Up, and a Wearable Device Project.

16. Plans for Tabulation and Publication and Project Time Schedule

The following are key activities and projected completion goals for the 2017-18 NHANES:

Activity	Projected Completion
• Planning survey content	Nineteen months before OMB approval
• 2017-18 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.