

Supporting Statement A for Request for Clearance

National Health and Nutrition Examination Survey

OMB No. 0920-0950
Expiration Date: 12/31/2019

Contact Information:

David Woodwell, MPH
Chief, Planning Branch
Division of Health and Nutrition Examination Statistics
National Center for Health Statistics/CDC
3311 Toledo Road
Hyattsville, MD 20782

Telephone: 301-458-4327
FAX: 301-458-4028

E-mail: DWoodwell@cdc.gov

November 16, 2018

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.....	11
4. Efforts to Identify Duplication and Use of Similar Information.....	11
5. Impact on Small Businesses or Other Small Entities.....	12
6. Consequences of Collecting the Information Less Frequently	12
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	12
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....	12
9. Explanation of Any Payment or Gift to Respondents.....	13
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.....	14
11. Institutional Review Board (IRB) and Justification for Sensitive Questions.....	18
12. Estimates of Annualized Burden Hours and Costs.....	21
13. Estimate of Other Total Annual Cost Burden to Respondents And Record Keepers.....	23
14. Annualized Cost to the Federal Government.....	23
15. Explanation for Program Changes or Adjustments.....	24
16. Plans for Tabulation and Publication and Project Time Schedule.....	24
17. Reason(S) Display of OMB Expiration Date is Inappropriate.....	24
18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	24

Attachment List

- Attachment 1 – Applicable Laws or Regulations (Excerpts)
- Attachment 2a – 60-Day Federal Register Notice
- Attachment 2b – Public Comments to the 60-day Federal Register Notice
- Attachment 3a – Summary of 2019-2020 Questionnaire Changes
- Attachment 3b – Screener
- Attachment 3c- Screener Hand Cards
- Attachment 3d – Household Interview
- Attachment 3e- Household Interview Hand Cards
- Attachment 3f – Mobile Exam Center (MEC) Interview and Examination
- Attachment 3g- MEC Computer Assisted Personal Interview (CAPI) & Dietary Recall (DRQ) Hand Cards
- Attachment 3h`- Telephone Dietary Recall and Dietary Supplements
- Attachment 3i – Flexible Consumer Behavior Survey (FCBS) Description
- Attachment 3j– FCBS Phone Follow-Up
- Attachment 3k – FCBS Hand Cards
- Attachment 3l – Questionnaires & Data Collection Forms 2017-2018
- Attachment 4 – Developmental Project Reports
- Attachment 5a - Laboratory Assessments 2019-2020 and earlier
- Attachment 5b - Laboratory Assessments 2017-18 and earlier
- Attachment 6 - Agencies consulted 2019-2020
- Attachment 7 – NHANES History
- Attachment 8a – Letters and Scripts
- Attachment 8b - 2018 Advance Letter
- Attachment 9a - Consent Forms
- Attachment 9b - Consent Brochure
- Attachment 9c - Assent Brochure

Attachment 9d - Deleted
Attachment 9e - assent 7-11
Attachment 9f - assent 12-17
Attachment 9g - e-consent Adult
Attachment 9h - Rev Transport Auth HC 17-18
Attachment 9i - NHANES Health Measurements
Attachment 9j - 2018 Auth for Transport
Attachment 9k - Confidentiality Brochure
Attachment 9l - Future Research non DNA English
Attachment 9m - Home Intv Consent English Final
Attachment 9n - NHANES Health Measurements
Attachment 9o - Child_Assent_Brochure_inside
Attachment 9p - MEC_Adult_ParentalConsentBrochure
Attachment 10 – Ethics Review Board (ERB) Approval
Attachment 11 – Human Papillomavirus Informational Flyer
Attachment 12 – Developmental Projects & Special Studies Testing
Attachment 13 – 24 hour BP pilot
Attachment 14a – Sample Design Tables 2019-2020
Attachment 14b – Sample Design 2015-2018
Attachment 15 - 3-5 Yr Urine Fact Sheet
Attachment 16 - Report of Findings
Attachment 17a – Example Background Materials
Attachment 17b – Example Background Materials
Attachment 18a- Make a Plan - multi color
Attachment 18b- Make a Plan tracker
Attachment 19a- NHANES Incentive Pilot Summary
Attachment 19b- NHANES Incentive Pilot Details
Attachment 20a DXA Crossover Study Description
Attachment 20a DXA Crossover Study Form

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 area 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 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, Exp. Date 12/31/2019). The program is requesting a three-year clearance.

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

The program is submitting this revision request to:

- Collect data in years 2019-2020,
- Collect follow-up data and conduct activities related to data collection/processing (for survey year 2020) through 2021,
- Conduct developmental projects to support data collection for 2021 and beyond,
- Conduct non-response projects as needed.

Brief summary of planned changes for the 2019-2020 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 2019-2020.

Adding/modifying in 2019-2020.

- Standing Balance and two vision tests to compliment balance (ages 40+)
- Words-In-Noise Test as part of audiometry (ages 70+)

- Automated Blood Pressure and pulse collection (transition dependent on sufficient crossover data)
- Cycling back in a cognitive function test (ages 60+)
- Two questions on WIC participation
- Birth to less than 24 month questionnaire
- Collecting information on infant and toddler formula, including information from formula labels
- Genetic testing related to the liver elastography exam
- Oral rinse samples for HPV analyses is cycling back into the survey (ages 14-69 years)
- Adding or modifying multiple laboratory components
- Modifying multiple questionnaire components
- Adding the Make-a-Plan tracking tool as a reminder resource for survey participants
- Cycling back in a home water sample collection
- Cycling back in eight thyroid biomarkers
- Adding a collection of salt used in the home
- Cycling back in the detection of tuberculosis (*Mycobacterium tuberculosis*) infection in whole blood
- Adding an incentive pilot for a newly added non-response bias module at the screening stage, and for the in-home interview stage
- Adding a crossover Dual X-ray Absorptiometry (DXA) study in order to replace aging equipment with newer models

The following analytes have been discontinued in 2018 for participants from the smoking sample subset:

- Aromatic Amines
- Heterocyclic Amines
- Urine Cotinine
- Tobacco-Specific Nitrosamines
- Perchlorate, Nitrates, and Thiocyanate
- Urinary Arsenic, Mercury, Iodine and Metals

Cycling Out of NHANES 2019-2020

- Blood pressure methodology project
- Human Papillomavirus (HPV) in serum
- Aldehydes in serum
- Volatile N-nitrosamines (VNAs) tobacco biomarkers
- Urine heterocyclic amines, urine aromatic amines and urine tobacco-specific nitrosamines

Please find a summary of changes to the questionnaire in Attachment 3a.

NHANES will continue to submit requests to conduct future developmental projects (i.e., pilot, feasibility or specials studies testing as well as methodological, equipment or other developmental testing) through non-substantive change requests, generic information collection requests (GenICs), or full revisions, as appropriate. These projects could include NHANES participants (present or past), members of the health care community (such as records retrieval staff, or health care providers etc.) as well as volunteers (non-NHANES participants) who may receive incentives or tokens of appreciation.

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 to:

1. Estimate the number and percentage of persons in the U.S. population and designated subgroups with selected diseases and risk factors,
2. Monitor trends in the prevalence, awareness, treatment and control of selected diseases,
3. Monitor trends in risk behaviors and environmental exposures,
4. Analyze risk factors for selected diseases,
5. Study the relationship between diet, nutrition and health,
6. Explore emerging public health issues and new technologies, and
7. 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. See below for additional details about the purposes and uses of the survey’s content.

The NHANES Interviews

We collect questionnaire data as stand-alone components or to complement one or more examination or laboratory components. Trained interviewers ask questionnaires in NHANES 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 the following major components:

1. Household Screener Questionnaire (determines eligibility) (SCQ) and the Non-Response Bias Module
2. Household Family Relationship Questionnaire (SFQ)
3. Household Sample Participant Questionnaire (HPQ)
4. Household Family Questionnaire (HFQ)
5. Mobile Examination Center (MEC) Questionnaire (CAPI and ACASI)
6. Mobile Examination Center Dietary Interview (24-Hour Dietary Recall, Post-Dietary Recall Questions and Dietary Supplements)
7. Telephone Dietary Recall and Dietary Supplements
8. Special Follow-Up Questionnaires (FCBS) (Phone)

Across the components, three new questionnaire sections will be added; two sections will be discontinued and 33 sections will be modified. Twenty sections will not be modified.

New Sections:

- Standing Balance (BDQ)
- Infant and Toddler Formula (IFQ)
- Salt Use (SUQ)

Dropped Sections:

- Physical Functioning (PFQ)
- Occupation (OCQ) in the Family Questionnaire

Attachment 3a provides a description of all questionnaire changes (including modifications) and the rationales for them. The complete set of 2019-2020 questionnaires (1-7 as described above), hand cards and the Flexible Consumer Behavior Survey are in Attachments 3b-3k. (The 2017-2018 questionnaires and hand cards are in Attachment 3l.) Each questionnaire attachment begins with a table of contents that lists questionnaire sections by their component name and corresponding 3 letter component abbreviation.

Below are brief descriptions of new questionnaire sections or new questions added to existing questionnaire sections as part of the birth to less than 24-month project.

Standing Balance (BDQ) (new)

NHANES is reintroducing a standing balance assessment for participants 40 years and older. An accompanying set of balance-related questions will quantify the participant's history of imbalance and falls to relate to their balance assessment measures

Infant and Toddler Formula (IFQ) (new)

A new section on infant and toddler formula is being added to NHANES and will involve capturing information from formula labels. Three questions will make up this new section (IFQ). These 3 questions are part of a larger set of 22 new questions all focused on a birth to less than 24 months cohort of participants.

The remaining birth to less than 24 months questions will be added to existing sections of the NHANES questionnaire. Seventeen will be asked in the existing Dietary Behavior and Nutrition

(DBQ) section. Two will be asked in the existing Early Childhood (ECQ) section.

The relationship of early child nutrition to health outcomes throughout the lifespan has grown as an important public health interest. From birth to 24 months (0-24 mo) is a critical life stage nutritionally because of the increased demand for nutrients to support growth and development. Early child nutrition impacts taste preferences, dietary behaviors, and the development of dietary patterns. Inadequate intake of nutrients, poor diet behaviors, and unhealthy weight gain in early childhood lead to numerous developmental and long-term health problems.

Traditionally, the Dietary Guidelines for Americans has focused on individuals ages 2 years and older. The Agricultural Act of 2014 has mandated that beginning with the 2020-2025 edition, the Dietary Guidelines includes comprehensive dietary recommendations for children 0-24 mo. As a result, nationally representative data on children 0-24 months are crucial to advancing the science base used to inform current and future Federal nutrition and related health programs, policies, and consumer information. Currently, the data captured in NHANES are not sufficient to conduct analyses needed to develop and monitor the implementation of nutrition and other health-related policies for children 0-24 mo. This questionnaire addresses three specific areas, 1) “mixed feeding” and “modes of feeding,” 2) introduction of first foods with a focus on the five main food groups, and 3) self-reported maternal pre-pregnancy height and weight for calculating pre-pregnancy BMI of the mothers of the child participants.

Salt Use (SUQ) (new)

The main sources of iodine in the U.S. include dairy products, eggs, baked goods, iodized table salt, and some dietary supplements. Without adequate intake of iodine, the thyroid gland cannot produce sufficient thyroid hormones and a spectrum of adverse effects can occur. Prior NHANES cycles have shown the iodine status of the general U.S. population has decreased by approximately half since NHANES III, and pregnant women in the U.S. have insufficient iodine intake. The health effects of mild iodine deficiency are not known.

Concerns about adequate intake are raised by dietary patterns where intake of some of these important sources may be low, as may occur in lactose-intolerant minority groups (notably African Americans, Asians, and Hispanics) or individuals choosing vegan or vegetarian diets. Furthermore, the current contribution of iodized household salt is not known but may be lower than in the past when more food was cooked at home. Adding questions about salt use, including information obtained by looking at the packaging for salt used in the home will help fill this data gap.

Incentive Pilot (New)

Given the continued declines in response rates to all survey stages, and the growing challenges associated with collecting high-quality and unbiased nationally representative data, NHANES would like to test the use of incentives for the newly added non-response bias module, which will be added to the screener stage in 2019, and to the selected participant (SP) in-home interview. The incentive pilot will be used to assess the impact of the incentives on data quality and non-response bias, response rates, and level of effort and cost. See Attachments 19a and 19b for more details (including information on sample design, data collection etc.).

NHANES Examination

NHANES Examination changes for 2019-2020 include:

- Adding a Standing Balance Test with two vision tests to compliment balance (ages 40+)
- Adding a Words-In-Noise Test (ages 70+)
- Cycling back in a cognitive function test (ages 60+)
- Cycling back in oral rinse samples for HPV (ages 14-69 years)
- Transitioning to automated Blood Pressure collection (provided sufficient crossover data to support this)
- Adding a crossover Dual X-ray Absorptiometry (DXA) study in order to replace aging equipment with newer models
- Dropping the Blood Pressure Methodology Project

See Attachments 3a for a summary of NHANES 2019-2020 questionnaire changes. See attachments 3b-3e for the screener and household interview, inclusive of the related hand cards. See Attachments 3f-3k for a summary of NHANES MEC questionnaires, exams and phone follow-up interviews (dietary recall and the Flexible Consumer Behavior Survey (FCBS)), along with corresponding hand cards. See Attachment 3l for data collection forms (including exam forms and hand cards) used in NHANES 2017-2018.

NHANES continues to monitor trends in the prevalence and treatment of many conditions with content included on the examination, laboratory and questionnaires. The following exam content continues from previous NHANES:

- Chronic Conditions
- Cardiovascular disease
- Diabetes Mellitus
- Obesity
- Chronic Liver Disease
- Dietary Assessment
- Osteoporosis
- HPV swabs in males and females

Below are brief descriptions of new or modified exam components.

Standing Balance (new)

NHANES is reintroducing a standing balance assessment for participants 40 years and older. This test is a modification over the test conducted in NHANES in 2001-2004. The purpose of the proposed exam is to measure how well older adults are able to maintain their balance while standing and to identify factors related to balance dysfunction by age, gender, and other demographic characteristics. Three measures will be conducted 1) a modified Romberg test for standing balance; 2) a vision contrast sensitivity test to assess vision impairment; and 3) a dynamic visual acuity test to identify vision/inner ear dysfunction. Information from this component will be used to investigate the public health burden of standing balance dysfunction. Balance issues contribute to falls among older adults and leads to bone fractures and reduced ability to walk, work, or function independently. A report in Attachment 4 summarizes our 2018 pilot test of the proposed methods which demonstrated the feasibility of conducting this standing balance assessment in 2019-2020 NHANES.

Audiometry (modified)

The target age group for the audiometry component is participants ages 6-19 and 70+. 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. In 2019-2020, a Words-In-Noise (WIN) component will be added to the existing audiometry component. The WIN exam will be completed using the audiometry software system, which is currently used for pure-tone threshold hearing test; and using the test recordings (pre-recorded stimuli) developed from the NIH Toolbox. During the test, the participant is asked to repeat a list of up to 35 words that are repeated during an increasingly loud background of multi-talker babble. Because correct WIN scoring is based on the health technician's ability to hear and record the participant's responses correctly, we will request participant consent to record their repeated words during the test. This will allow double scoring (and adjudication when scoring differs) to improve reliability of the WIN scores. Recording of the study participants responses will be managed by the audiometry software.

Cognitive Function (returning)

NHANES is reintroducing a cognitive functioning assessment. Cognitive functioning consists of multiple domains including executive function, episodic memory, working memory, processing speed, language, and attention. The brief neuropsychological assessment of cognitive functioning proposed for inclusion in NHANES allows for a more extensive assessment than the cognitive assessment measures previously used in NHANES. Cognitive status will be assessed among participants 60 years and older using the 18 item survey adaption of the Montreal Cognitive Assessment-Survey Adapted (MOCA-SA) (Attachment 3f). The MOCA-SA is designed for administration by non-medical personnel within the context of a larger time-limited survey. The addition of cognitive measurements is designed to advance the goals of NHANES to estimate the national prevalence of selected diseases and risk factors and contribute to understanding the distributions of select health characteristics across populations. Additionally, this provides an opportunity to examine prevalence, morbidities, and co-morbidities of cognitive functioning using combinations of physical, psychological and social variables not available simultaneously from other data sources.

Oral Health (modified)

The target age group for the Oral Health component continues to be participants ages 1 and older. NHANES will continue to collect information on tooth retention and loss, tooth decay (ages 1+), dental restorations (ages 18+), and dental sealants (ages 3-19). In 2019-2020, NHANES is cycling back into the survey an oral rinse for Human Papilloma Virus (HPV) among participants 14-69.

DXA Crossover Study (New)

NHANES has been conducting DXA scans since 1988. The equipment currently in the field is reaching its 'life expectancy' as they have been in use on the MECs since 2010 and the manufacturer has recently informed us that they will no longer support maintenance on these aging devices. For these reasons, the Division of Health and Nutrition Examination Surveys (DHANES) needs to deploy new DXA densitometers. The purpose of this project is to collect data that will allow NHANES to assess the impact of switching to new DXA densitometer units (Discovery vs. Horizon). Comparing data from the new machines with data from the older model currently in the field, using the same volunteers, will help assure that any future changes in osteoporosis prevalence and body composition would be due to population changes and not simply due to the switch to using new DXA units and scan acquisition software. Recalibrate method will be used to calibrate the old and new machines. Deming regression will be used to derive conversion equations from old systems to be equivalent to referent system.

The objectives of this project are:

- To conduct DXA scans on 30 volunteers (15 men and 15 women), between the ages of 20-70, using the current NHANES DXA machines
- To conduct DXA scans on 30 volunteers (15 men and 15 women), between the ages of 20-70, using the proposed new NHANES DXA machines

The outcome measures for this project will include:

- Comparing data from the same individuals on both DXA machines to assess differences in measurements
- Documenting changes between machines to prevent such changes from erroneously having an impact on osteoporosis prevalence and body composition measure in NHANES
- Conversion equation will be derived and used for future scan analysis.

The burden for this project, 50 minutes per participant, is already captured in line 6 of the burden table below (Developmental Projects & Special Studies) See Attachment 20a and 20b for more details on the DXA Crossover Study.

NHANES Laboratory Assessments

Laboratory Assessment changes for 2019-2020 include:

New Laboratory Tests in 2019

- Environmental toxicants in whole blood: two volatile organic compounds (VOC);
 - o Hexanone and α -Pinene;
- Environmental toxicants in urine: two personal care and consumer product chemicals and metabolites;
 - o Hydroxy Butyl paraben and Di-hydroxy avobenzone.
- One insect repellent: DEET metabolite; one flame retardant; six neonicotinoid insecticide biomarkers; two organophosphorus insecticides: two dialkyl phosphate metabolites; and one volatile organic compound (VOC) metabolite;
- Trace element in salt sample: iodine in salt;
- Nutritional biomarker in serum: one vitamin E metabolite;
- Nutritional biomarker in whole blood: 32 RBC fatty acids, and six RBC folate forms;
- Steroid hormones in serum: six steroid hormones;
- Hemoglobinopathies in whole blood: four hemoglobin variants;

Modified Laboratory Tests in 2019

- Environmental toxicants in urine: eleven tobacco biomarkers (one tobacco-specific nitrosamines and ten heterocyclic aromatic amines) are cycling back in from a previous NHANES cycle;
- Environmental toxicants in serum: ten per- and polyfluoroalkyl substances have a change in subsample, polybrominated diphenyl ethers, polychlorinated dibenzo-p-dioxins and dibenzofurans, polychlorinated biphenyls (PCBs), organochlorine pesticides, dioxins, and furans change from pooled to individually-tested samples;
- Trace element in water sample: fluoride in water is cycling back from a previous NHANES cycle;

- Human Papillomavirus Virus (HPV) in oral rinse: thirty-seven HPV types are cycling back in from a previous NHANES cycle;
- Steroid Hormone in serum: testosterone and estradiol cycling back in from a previous NHANES cycle;
- Thyroid Panel in serum: eight thyroid biomarkers are cycling back in from a previous NHANES cycle
- Tuberculosis (Mycobacterium tuberculosis) infection in whole blood: detection of tuberculosis (M. tuberculosis) infection in whole is cycling back in from a previous NHANES cycle (foreign-born participants ages 12-59; and all participants ages 60+)
- Liver Disease Genetics Markers: cycling back in from a previous NHANES cycle

Dropped Laboratory Tests in 2019

- One volatile organic compound (VOC) in whole blood;
- One DEET metabolite in urine;
- Four (ALL) aliphatic diamines from the diisocyanates metabolites and urinary amines chemical group in urine

Continuing Laboratory Tests in 2019-2020

- Pregnancy Tests (urine) (female participants ages 8-59)
- Hematology (Complete Blood Count) (all participants 1+)
- Metals: Lead, cadmium, mercury, mercury speciation, selenium and manganese in whole blood (all participants 1+)
- Chromium and Cobalt (all participants 40+)
- Folates and Folate Forms in whole blood and serum (all participants 1+)
- Cytomegalovirus (CMV) in serum (all participants 1-5)
- Ferritin in serum (all participants 1-5 and 12+)
- Transferrin Receptor in serum (all participants 1-5 years old; and female participants 12-49)
- Vitamin D in serum (all participants 1+)
- Vitamin, A, E, C and carotenoids in serum (all participants 6+)
- Fasting glucose in plasma and Insulin in serum (all morning participants 12+) and Glycohemoglobin in whole blood (all participants 12+)
- Total and HDL Cholesterol in serum (all participants ages 6+)
- LDL Cholesterol and Triglycerides in serum (all participants ages 12+)
- Standard Biochemistry Profile, iron and iron binding in serum (all participants ages 12+)
- Urinary Albumin and Creatinine, Albumin/Creatinine Ratio, and Urine Flow Rate (all participants 3+) in urine
- C-Reactive Protein (high-sensitivity) in serum (all participants 1+)
- Hepatitis viruses (all participants 6+); anti-HBs (all participants ages 2-5 only) in serum
- Chlamydia trachomatis (all participants ages 14-39) and Trichomonas vaginalis (all participants ages 14-59) in urine
- Herpes Simplex 1 and 2 in serum (all participants ages 14-49)
- Human Immunodeficiency Virus in serum (HIV) (all participants ages 18-59)

- Human Papillomavirus Virus (HPV) (vaginal and penile swabs and serum) (all participants ages 14-59)

Environmental Chemical Exposures:

- Adducts of Hemoglobin: Acrylamide, Glycidamide, Ethylene Oxide, and Formaldehyde (Packed Cells) (1/3 subsample ages 6+)
- Dioxins, persistent organic pollutants (POPs), brominated flame retardants (BFRs) and per- and polyfluoroalkyl substances (PFASs), in serum (1/3 subsample ages 12+)
- Aromatic Diamines (formerly Diisocyanates Metabolites and Urinary Amines) (Urine) (all participants ages 3-5 and 1/3 subsample ages 6+)
- Metals (Urine) (all participants ages 3-5 and 1/3 subsample ages 6+)
- Perchlorate, Nitrate, Thiocyanate (Urine) (all participants ages 3-5, 1/3 subsample ages 6+, and all smokers ages 20+)
- Pyrethroid Pesticides, Herbicides, and Organophosphate Insecticides Metabolites (Urine) (all participants ages 3-5 and 1/3 subsample ages 6+)

See Attachment 5a for the 2019-2020 and earlier Laboratory Assessment tables. See Attachment 5b for the 2017-18 and earlier Laboratory Assessment tables. See Attachment 15 for the 3-5 year old urine fact sheet provided to parents.

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, laboratories, and NCHS headquarters, etc. 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. No other studies 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. The agencies consulted for NHANES 2019-2020 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 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

A 60-day Federal Register Notice was published on May 11, 2018, volume 83, number 92, pp. 22069 – 22071. CDC received five comments in total, two of which were nonsubstantive. See Attachments 2a and 2b respectively for a copy of the notice and comments.

b. Outside Consultation

NHANES is a collaborative undertaking. The program seeks broad input from the research community, academia, federal agencies and other interested parties to maximize the utility of the survey data. NHANES consults with its collaborators and interested agencies through meetings, conference calls or via email. The program uses a formal research proposal solicitation process prior to future content planning and development.

The program published proposal guidelines for new 2019-2020 content on the NHANES website. Division of Health and Nutrition Examination Surveys (DHANES) staff sent members of the NHANES user community letters inviting them to submit research proposals. In addition, the program sent correspondence to dozens of persons who indicated their interest in being kept informed of NHANES activities. DHANES received over 25 proposals in response to this solicitation process.

NCHS staff gave 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 provided 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 received incentives as a token of appreciation for their examination participation since the 1970s. The 2019-2020 NHANES incentives are below. They are the same as those used in 2018.

Examination incentive

Subgroup	2019-2020 Incentive
16 and older agreeing to assigned session	\$125
16 and older not agreeing to assigned session	\$90
12-15 agreeing to assigned session	\$75
12-15 not agreeing to 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 allowed to receive \$5.25 an hour for up to 6 hours to help with out of pocket costs. Participants also receive help with out of pocket costs related to transportation for driving to the MEC, or for when a taxi is needed.

Incentives to help participants with out-of-pocket transportation costs

TRANSPORTATION Related Incentives 2019–2020		
Incentives to help with Subject Participant (SP) Transportation - 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).

During 2019-2020, NHANES may request permission to test staggered incentive in an effort to address decreasing response rates. The response rates for participants examined in 2017 was 52%. Attachment 7 contains a graph of NHANES examination response rates from 1999-2016 as well as a brief history of NHANES incentives

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 August 21, 2017.

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 U.S.C. 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA, Title 5 of Public Law 107-347). In accordance with CIPSEA every NCHS employee, contractor and agent have taken an

oath and is subject to a jail term of up to five years, a fine of up to \$250,000, or both if he or she willfully discloses ANY identifiable information about you. In addition, NCHS complies with the Cybersecurity Enhancement Act of 2015 (6 U.S.C. §§ 151 & 151 note) . This law requires the Federal government to protect federal computer networks by using computer security programs to identify cybersecurity risks like hacking, internet attacks, and other security weaknesses. If information sent through government networks triggers a cyber threat indicator, the information may be intercepted and reviewed for cyber threats by computer network experts working for, or on behalf of, the government.

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 2019-2020, 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 activities 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 8a and 8b)
Household Screener Questionnaire (Attachments 3b),
Household Relationship Questionnaire (Attachment 3b)
Household/Family Questionnaire (Attachment 3d)
Household Sample Person Questionnaire (Attachment 3d)
MEC Data Collection Forms (Attachments 3f and 3g)
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)
Assents (Attachments 9e and 9f)
Electronic Consent (Attachment 9g)

Several attachments were revised in 2018 due to requests for changes from the NCHS Ethics Review Board (ERB). The revised documents are in Attachments 8b and 9h through 9p.

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. See below for additional information about the information collected in the

examination, laboratory assessments and interviews.

NHANES Examination

- Cardiovascular Health
- Diabetes Mellitus
- Dietary Assessment
- Oral Health, including oral HPV
- Hearing, including Words-in-Noise
- Body composition and bone density
- Osteoporosis
- Balance
- Cognitive Function

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

Please see “A.11 Justifications for Sensitive Questions” for more details.

The NHANES continues to collect personally identifying information (PII), on a confidential basis, needed to re-contact respondents and to match respondents to administrative records such as the National Death Index (OMB. No. 0920-0215, Exp. Date 12/31/2019). 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.

NHANES mails an Advance letter (Attachments 8a and 8b) to each household in the sample segments announcing the upcoming 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 the 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. However, NHANES does not release confidential data 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, to assure that directly or indirectly identifiable data are not included in public releases.

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 10/26/2018 (see Attachment 10).

Descriptions of self-reported and objective data of a sensitive nature are as follows.

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 2019-2020 NHANES will continue to use the SSN to link with the Supplemental Nutrition Assistance Program (SNAP) (previously called the Food Stamp Program) and Women, Infants and Children (WIC) Program administrative records from the USDA.

Permission to link is obtained from respondents as follows:

In the Household:

“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. There will be no effect on {your/his/her} benefits if you do not provide it. What is {your/SP's} Social Security Number?”

If the respondent is reluctant or need more information, the following text is read:

“I understand your concern. By matching NHANES data with other health-related records, researchers can study health conditions like heart attacks and diabetes in depth. They can also better understand health care use and health care costs for all Americans. These findings will help doctors assist patients in making smart choices. Here are other examples (HAND CARD DMQ8) of things we have learned when we matched records from different sources. May I please have {your/SP's} Social Security Number?”

In the MEC:

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

If the respondent is reluctant or need more information, the following text is read:

“I understand your concern. Would you provide us with the last four digits of {your/SP's} Social Security Number? This information will allow researchers to match NHANES survey data with health-related records to study important things like changes in health status, eating patterns and health care costs. [May I have the last four digits of {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.

The question is asked 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}. Providing the Health Insurance Claim Number is voluntary and collected under the authority of the Public Health Service Act. Whether the number is given or not, there will be no effect on {your/his/her} benefits. This number will be held confidential. [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.

The NCHS Ethics Review Board (formerly called the NCHS Institutional Review Board) reviews all questions and procedures (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 sensitive are listed below. Most of these are questions commonly asked in health care settings. NHANES asks sensitive questions in private settings within the Mobile Examination Center (MEC).

- 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 audio computer-assisted self-interview (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 table below shows the estimated annual burden for each survey component within this submission, totaling 67,917 hours. The total estimated burden for one year of NHANES is 32,417 hours, including screening, household interview, examination and follow-up interviews (lines 1-5 of the table below). The remaining 35,500 hours of burden are for developmental projects, pilots, work in advance of special studies, etc.

The annual estimated burden for the various components of NHANES are below: The NHANES screener (attachment 3b) is budgeted for 5 minutes -- the maximum number of respondents would be 15,000 and the maximum burden 1,250 hours. The NHANES household interview (Attachment 3d) is budgeted for 1.5 hours -- the maximum number of respondents would be 5,000 and the maximum burden 7,500. The NHANES MEC Interview and Examination (Attachment 3f) is budgeted for 4 hours -- the maximum number of participants would be 5,000 and the maximum burden 20,000 hours. The Telephone Dietary Recall and Dietary Supplements (Attachment 3h) is budgeted for 30 minutes -- the maximum number of respondents would be 5,000 and the maximum burden 2,500 hours. The Flexible Consumer Behavior Survey Phone Follow-Up (Attachments 3i) is budgeted for 20 minutes -- the maximum number of respondents would be 5,000 and the maximum burden 1,667 hours. Adult respondents who participate in all of the above aspects of NHANES can expect a total estimated burden of up to 6.4 hours.

Up to 3,500 additional persons (including non-NHANES respondents) might participate in Developmental projects (such as pilot tests or methodological studies) or testing ahead of Special Studies, if budgeted. The average burden for these respondents is 3 hours (Attachment 12). The estimated total burden for one year for special studies is 10,500 hours. Up to 1,000 additional persons (including non-NHANES respondents) might participate in a 24-hour blood pressure monitoring project. The average burden for these respondents is 25 hours (Attachment 13). The estimated total burden for one year for would be 25,000 hours.

The new requested burden for this submission is 68,417 hours, a reduction of 11,477 hours. The burden table has been reformatted, compared to previous submissions. It now shows each level of possible participation (screener, interview, exam, post exam etc.) in NHANES as a separate line item. (Past clearance documents used an average participant burden across all the possible levels of participation.) The reduction in the burden estimates for the main parts of NHANES (screener through post MEC interviews) is because the questionnaire instruments have been streamlined. The 24-hour blood pressure pilot represents a new burden request.

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 (in hours)
Individuals in households	Screeners	15,000	1	5/60	1,250
Individuals in households	Household Interview	5,000	1	1.5	7,500
Individuals in households	MEC Interview & Examination	5,000	1	4	20,000
Individuals in households	Telephone Dietary Recall & Dietary Supplements	5,000	1	30/60	2,500
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	24 hour Blood Pressure Pilot	1,000	1	25	25,000
Total					68,417

b. Cost to Respondents

The hourly wage rate of \$23.86 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 given an incentive as a token of appreciation for their time and to help with out of pocket expenses such as childcare and transportation.)

TABLE 2 – Cost to Respondents

Type of Respondent	Form Name	Total Burden (in hours)	Hourly Wage Rate	Total Respondent Costs
Individuals in households	Screener	1,250	\$23.86	\$29,825
Individuals in households	Household Interview	7,500	\$23.86	\$178,950
Individuals in households	MEC Interview & Examination	20,000	\$23.86	\$477,200
Individuals in households	Telephone Dietary Recall & Dietary Supplements	2,500	\$23.86	\$59,650
Individuals in households	Flexible Consumer Behavior Survey Phone Follow-Up	1,667	\$23.86	\$39,775
Individuals in households	Developmental Projects & Special Studies	10,500	\$23.86	\$250,530
Individuals in households	24 hour Blood Pressure Pilot	25,000	\$23.86	\$596,500
Total		68,417		\$1,632,430

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 45 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 overhead	\$6,000,000
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 for this submission is 68,417 hours, a reduction of 11,477 hours. The burden table has been reformatted, compared to previous submissions. It now shows each level of possible participation (screener, interview, exam, post exam etc.) in NHANES as a separate line item. (Past clearance documents used an average participant burden across all the possible levels of participation.) The reduction in the burden estimates for the main parts of NHANES (screener through post MEC interviews) is because the questionnaire instruments have been streamlined. The 24-hour blood pressure pilot represents a new burden request.

16. Plans for Tabulation and Publication and Project Time Schedule

The following are key activities and projected completion goals for the 2019-2020 NHANES:

Activity	Projected Completion
• Planning survey content	Nineteen months before OMB approval
• 2019-2020 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.