

NHANES – Supporting Statement – Section A.

Section A Supporting Statement for Request for Clearance

National Health And Nutrition Examination Survey

2009-2010

OMB No. 0920-0237 (expires November 30, 2009)

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October 17, 2008

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## NHANES – Supporting Statement – Section A.

### A. Justification

#### 1. Circumstances Making the Collection of Information Necessary

The National Center for Health Statistics (NCHS), Division of Health and Nutrition Examination Surveys (DHANES), Centers for Disease Control and Prevention (CDC) is seeking a three-year approval to continue the National Health and Nutrition Examination Survey (NHANES) (OMB # 0920-0237 expires November 30, 2009)), and specifically to collect data for 2009-2010, to conduct special studies to test data collection for 2011 and beyond or to conduct community HANES (CHANES).

#### **For 2009, the new examination, laboratory and questionnaire topics include:**

- The introduction of an examination component for inflammatory back pain and spondyloarthritis, a form of spinal arthritis. A U.S. population-based evaluation of spondyloarthritis has never been performed, primarily because effective treatments were not previously available. This task becomes more urgent with the recent discovery that biologic chemotherapy can dramatically improve the course of the disease. (A, 2, NHANES Examination Components, g, p.12)
- The return of an audiometry (hearing) assessment for participants 70 and older in the MEC examination. This data will allow estimates of hearing loss in this age group to be updated. (A, 2, NHANES Examination Components, h, p.13)
- The 2009-2010 oral health component has substantial changes from 2007-8. Assessment of dental fluorosis and periodontal disease will return to the examination for the first time since 2004. Additionally, a rinsed specimen will be obtained to test for oral Human Papilloma Virus (HPV) infection (A, 2, NHANES Examination Components, e, p. 11).
- Introduction of the Reactions to Race questionnaire. This module will gather information about respondents' perceptions of how they are treated based on race/ethnicity and whether or not these perceptions impact their health. These data contribute to the major NHANES objectives of studying health disparities and factors that may contribute to these disparities. (A, 2, The NHANES Interviews, p.23)

The Inflammatory Back Pain/Spondyloarthritis and the Reactions to Race questionnaire will have been pilot tested prior to 2009-10 data collection. The status of the pilot tests as of preparation date of this package are in section B.4.

The vision and ophthalmology examination components are being cycled out in 2009. We have collected 10 and 4 years of data on these components, respectively.

#### Background

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

The NHANES were conducted on a periodic basis from 1971 to 1994. NHANES became a

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continuous, annual survey program in 1999. Each year, a nationally representative sample of the civilian, non-institutionalized U.S. population, all ages, is interviewed and examined. The response rates, for participants both interviewed and examined, for 2007 and 2008 to date are 74% and 75% respectively. Innovative recruitment methods and remuneration have contributed to the high response rates over the years. However, it is increasingly difficult to maintain high response rates and we have experienced a decline from 2005-6 when the response rate was 77%. We are requesting a remuneration adjustment.

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

The continuous data collection requires that pilot tests of new or revised survey material be conducted during the ongoing data collection. NHANES will continue to request permission to conduct pilot studies through the use of the OMB Change Form.

A major advantage of continuous NHANES data collection is the ability to address emerging public health issues and provide objective data on additional health conditions and issues.

NHANES continues to report on major public health topics in a timely and efficient manner. Examples of contributions reported by NHANES users since the last OMB submission 2 years ago are listed below:

- Estimates based on NHANES 2005-2006 data were published in the first six reports of a new NCHS report series entitled *NCHS Data Briefs*. These were published between November 2007 and May 2008. *NCHS Data Briefs* are concise, accessible summaries of current public health topics written to target nontechnical audiences, especially those who engage in health policy and health programs. Highlights of the six reports utilizing NHANES data include: 1) although the prevalence of obesity among adults remains high there was no statistically significant change in prevalence since 2003-2004; 2) average serum total cholesterol fell to 199 mg/dL in 2005-2006, meeting the Healthy People 2010 objective for reducing serum cholesterol levels among adults; 3) the prevalence of hypertension has remained stable over the period 1999-2006; 4) approximately one-half of 1% of the U.S. household population aged 18-49 years is infected with HIV; 5) breast feeding rates have increased in the U.S.; and 6) the folate status of the US population has remained stable, since the increase that initially occurred after folate fortification of foods.
1. Ogden CL, Carroll MD, McDowell MA, Flegal KM. Obesity among adults in the United States- no statistically significant change since 2003–2004. NCHS data brief no 1. Hyattsville, MD: National Center for Health Statistics. 2007.  
<http://www.cdc.gov/nchs/data/databriefs/db01.pdf>
  2. Schober SE, Carroll MD, Lacher DA, Hirsch R. High serum total cholesterol— an indicator for monitoring cholesterol lowering efforts; U.S. adults, 2005–2006. NCHS data brief no 2, Hyattsville, MD: National Center for Health Statistics. 2007.  
<http://www.cdc.gov/nchs/data/databriefs/db02.pdf>
  3. Ostchega Y, Yoon SS, Hughes J, Louis T. Hypertension Awareness, treatment, and control – Continued disparities in adults: United States, 2005-2006. NCHS data brief no 3, Hyattsville, MD: National Center for Health Statistics. 2008.  
<http://www.cdc.gov/nchs/data/databriefs/db03.pdf>

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4. McQuillan G, Kruszon-Moran D. HIV infection in the United States household population aged 18-49 years: Results from 1999-2006. NCHS data brief no 4, Hyattsville, MD: National Center for Health Statistics. 2008.  
<http://www.cdc.gov/nchs/data/databriefs/db04.pdf>
  5. McDowell MA, Wang C-Y, Kennedy-Stephenson J. Breastfeeding in the United States: Findings from the National Health and Nutrition Examination Surveys 1999-2006. NCHS data briefs, no. 5, Hyattsville, MD: National Center for Health Statistics. 2008.  
<http://www.cdc.gov/nchs/data/databriefs/db05.pdf>
  6. McDowell MA, Lacher DA, Pfeiffer CM, Mulinare J, Picciano MF, Rader JI, et al. Blood folate levels: The latest NHANES results. NCHS data briefs, no. 6, Hyattsville, MD: National Center for Health Statistics. 2008.  
<http://www.cdc.gov/nchs/data/databriefs/db06.pdf>
- Since the release of the *Third National Report on Human Exposure to Environmental Chemicals*, the National Center for Environmental Health, Centers for Disease Control and Prevention has published peer-reviewed articles with biomonitoring results for the U.S. population for the following chemicals: brominated flame retardants, environmental phenols (including triclosan and bisphenol A), total and speciated arsenic, perfluorinated compounds, and perchlorate. (These results will also be included in future *Reports*.) The articles are listed below. These can be accessed electronically at:  
[http://www.cdc.gov/exposurereport/biomonitoring\\_results.htm](http://www.cdc.gov/exposurereport/biomonitoring_results.htm)
1. Sjödin A, Wong LY, Jones RS, Park A, Zhang Y, Hodge C, DiPietro E, McClure C, Turner WE, Needham LL, Patterson DG Jr. Serum Concentrations of Polybrominated Diphenyl Ethers (PBDEs) and Polybrominated Biphenyl (PBB) in the United States Population: 2003-2004. *Environ Sci Technol* 2008;42(4):1377-84.
  2. Calafat AM, Wong LY, Ye X, Reidy JA, Needham LL. Concentrations of the Sunscreen Agent, Benzophenone-3, in Residents of the United States: National Health and Nutrition Examination Survey 2003-2004. *Environ Health Perspect* doi:10.1289/ehp.11269 available at <http://dx.doi.org/> [Online 21 March 2008]
  3. Calafat AM, Ye X, Wong LY, Reidy JA, Needham LL. Urinary Concentrations of Triclosan in the U.S. Population: 2003-2004. *Environ Health Perspect* 2008 Mar;116(3):303-7.
  4. Calafat AM, Ye X, Wong LY, Reidy JA, Needham LL. Exposure of the U.S. Population to Bisphenol A and 4-*tertiary*-Octylphenol: 2003-2004. *Environ Health Perspect* 2008 Jan;116(1):39-44.
  5. Caldwell KL, Jones RL, Verdon CP, Jarrett JM, Caudill SP, Osterloh JD. Levels of urinary total and speciated arsenic in the U.S. population: National Health and Nutrition Examination Survey 2003-2004. *J Expo Sci Environ Epidemiol*. doi:10.1038/jes.2008.32 available at <http://www.nature.com/jes/journal/vaop/ncurrent/full/jes200832a.html> [Online 4 June 2008]
  6. Calafat AM, Wong LY, Kuklennyik Z, Reidy JA, Needham LL. Polyfluoroalkyl Chemicals in the U.S. Population: Data from the National Health and Nutrition Examination Survey

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(NHANES) 2003-2004 and Comparisons to NHANES 1999-2000. *Environ Health Perspect* 2007 Nov;115(11):1578-83.

7. Calafat AM, Kuklennyik Z, Reidy JA, Caudill SP, Tully JS, Needham LL. Serum concentrations of 11 polyfluoroalkyl compounds in the U.S. population: data from the National Health and Nutrition Examination Survey (NHANES) 1999-2000. *Environ Sci Technol* 2007;41(7):2237-42.

Other examples of NHANES contributions in the last two years include the following:

- The prevalence of chronic kidney disease rose from 10.0% (95% confidence interval [CI], 9.2%-10.9%) in 1988-1994 to 13.1% (95% CI, 12.0%-14.1%) in 1999-2004. Chronic kidney disease prevalence was determined based on persistent albuminuria and decreased estimated glomerular filtration rate (GFR). "A higher prevalence of diagnosed diabetes and hypertension and higher body mass index explained the entire increase in prevalence of albuminuria but only part of the increase in the prevalence of decreased GFR." (*JAMA*. 2007;298(17):2038-2047)
- Using human papilloma virus (HPV) data from vaginal swabs obtained from girls and women ages 14-59 years in the 2003-4 NHANES, it was shown that overall HPV prevalence of infection was 26.8%; for the age group 20-24 years the prevalence of infection was 44.8%. (*JAMA*. 2007 Feb;297(8):813-9.)
- Prescription medication data from 1998-1994 and the 1999-2002 showed that the age-adjusted prevalence of psychotropic medication use increased from 6.1% in 1988-1994 to 11.1% in 1999-2002 ( $p < 0.001$ ), primarily due to a three-fold increase in antidepressant use (2.5%, 1988-1994 vs. 8.1%, 1999-2002 ( $p < 0.001$ )). (*Pharmacoepidemiology and Drug Safety*, 2007;16:560-570.)
- "In 1999-2002, 31.8% of children used dietary supplements, with the lowest use reported among infants younger than 1 year (11.9%) and teenagers 14 to 18 years old (25.7%) and highest use among 4 to 8-year-old children (48.5%). Use was highest among non-Hispanic white (38.1%) and Mexican American (22.4%) participants, lowest among non-Hispanic black participants (18.8%), and was not found to differ by sex. The type of supplement most commonly used was multivitamins and multiminerals (18.3%)." (*Arch Pediatr Adolesc Med*. 2007;161:978-985.)
- Oral health status has been measured on virtually all NCHS health examination surveys. The recent Vital and Health Statistics report provides detailed data on oral health status for the periods 1988-94 and 1999-2004. For Americans age 6 years and older, oral health has improved. For children age 2-5 years, the prevalence of caries has increased. (*Vital and Health Statistics Series, Series 11, No. 248. Trends in Oral Health Status: United States, 1988-1994 and 1999-2004*. 104 pp. (PHS) 2007-1698.)
- The 2005-06 NHANES bowel health data were presented at the NIH State-of-the-Science Conference on Prevention of Fecal and Urinary Incontinence in Adults on December 10-12, 2007. The NHANES data are the first nationally representative data collected on fecal incontinence in the U.S. Fecal incontinence can have a devastating impact on quality of life; its effects may include embarrassment, social isolation, and even loss of employment. Additionally, 3 posters presenting the NHANES bowel health data in more detail were shown at Digestive Disease Week, May 17 – 22, 2008. *Digestive Disease*

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Week is the world's largest gathering of physicians and researchers in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Published papers on the NHANES incontinence data are forthcoming.

The continuous survey design also makes early availability of the data possible. The first release of NHANES 2005-2006 data occurred in November, 2007. In planning for 2009-2010 we have tried to take maximum advantage of the abilities of all software used in data collection to reduce data review and editing required after data collection. We hope to continue to exceed our data release date goal and to have a greater proportion of the NHANES data released within a year of ending the data collection.

### Authorization

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

- a) Section 306 of the Public Health Service Act (42 U.S.C. 242k) directs the National Center for Health Statistics to collect statistics on subjects such as: the extent and nature of illness and disability of the population; environmental, social and other health hazards; and determinants of health.
- b) Section 4403 (Joint Nutrition Monitoring And Related Research Activities) of the Food, Conservation, and Energy Act of 2008 (P.L. 110-234) specifies that the Secretary and the Secretary of Health and Human Services shall continue to provide jointly for national nutrition monitoring and related research activities carried out as of the date of enactment of this Act.
- c) The Food Quality Protection Act of 1996 (P.L. 104-170) requires the implementation of surveys to collect data on food consumption patterns of infants and children and data on dietary exposure to pesticides among infants and children.
- d) Title 21 – Food and Drugs, Chapter 9 of the Federal Food, Drug, and Cosmetic Act (21 USC 393) authorizes the collection of information to support the Food and Drug Administration's objective to obtain current, timely, and policy-relevant consumer information to carry out its statutory functions.

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

### Information in Identifiable Form (IIF)

The following Information in Identifiable Form (IIF) will be collected:

- Name
- Date of Birth
- Social Security Number (SSN)



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- Medicare Beneficiary Number
- Biometric Identifiers
- Mother's Maiden Name
- Mailing Address
- Phone Numbers
- Medical Information and Notes
- Medical Records Numbers
- Biological Specimens
- Employment Status

These items have been approved and collected for more than a decade. Some of these are described in detail in A.11.

### 2. Purpose and Use of the Information Collection

The major objectives of NHANES are:

1. To estimate the number and percent 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,
7. To establish a national probability sample of genetic material for future genetic research, and
8. To establish and maintain a national probability sample of baseline information on health and nutritional status.

The purposes and uses of each survey component are detailed below. The major components of NHANES are the health examination component (A, 2, p. 9), the laboratory component (A, 2, p. 13), and the interview component (A, 2, p. 23). Additionally, the household interviewer collects a tap water specimen (Environmental Chemicals, A. 2. a Perchlorate and volatile organic compounds and B, 2., Data Collection) after the household interview, a second urine sample (A, 2, NHANES Laboratory Assessments, f, p. 23) is requested to be sent from home after the examination and the second dietary interview (A, 2, NHANES Examination Component, p. 10) plus other food consumption interview questions are asked during a telephone interview after the examination.

#### NHANES Examination Component

The major new examination component for 2009 is Inflammatory Back Pain/Spondyloarthritis, which is found in section (g.)

The oral health component, (found in section (e.)) and the audiometry component (found in section (h.)), have been modified. Other changes to components are highlighted in the component descriptions, if a change is not mentioned; the component is the same as was fielded in 07-08.

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The vision and ophthalmology examination components are being cycled out in 2009. We have collected 10 and 4 years of data on these components, respectively.

### a. Cardiovascular Health

The primary objectives of this component are to monitor the prevalence and trends in major cardiovascular conditions and risk factors in the U.S, and to evaluate prevention and treatment programs targeting cardiovascular disease in the U.S. The main elements of the cardiovascular disease component in NHANES are measurement of blood pressure and blood total cholesterol, HDL-cholesterol, LDL-cholesterol, Triglyceride, and Apo (B) levels. Information about treatment for hypertension and hyperlipidemia, including information about primary prevention will be collected by questionnaire. Other related risk behaviors such as obesity, tobacco use and exposure, physical activity and diet will be major components of NHANES. The data will be used to monitor the status of hypertension prevalence, awareness, treatment and control and the success of the National High Blood Pressure Education Program. Laboratory results will be used to monitor the prevalence of hyperlipidemia and the effectiveness of the National Cholesterol Education Program (NCEP).

### b. Diabetes Mellitus

Approximately one-third of diabetes is undiagnosed, based on data from NHANES. An additional segment of the population is at high risk for diabetes because they have pre-diabetes. Recent clinical trials have shown that diabetes can be delayed or prevented in persons with pre-diabetes. The fasting and two-hour blood glucose assessments will allow surveillance of the trends in the prevalence of diabetes and impaired glucose tolerance. Fasting insulin will identify the population at risk for developing diabetes and be a component in assessing insulin resistance and the prevalence of the metabolic syndrome. Measurement of glycohemoglobin (HbA1c) will assess the level of blood glucose control in the diabetic population.

The household questionnaires will include questions about awareness, and treatment. This information, along with the laboratory tests, will be used to assess progress in the achievement of the goals of the National Diabetes Education Program.

### c. Dietary Assessment

Dietary information has been collected in NHANES since the 1970s. Policy makers and researchers use NHANES dietary data to assess the quality and adequacy of the U.S. diet in relation to health parameters; to evaluate the impact of program changes including welfare reform, food fortification policy, and child nutrition programs; and to identify target groups for public health education and awareness programs.

All NHANES examinees are eligible to complete two dietary recall (DR) interviews. The first DR will be conducted in-person in the MEC dietary interview room by trained dietary interviewers. The second will be conducted by trained telephone dietary interviewers. Additionally, a 24-hour intake of dietary supplements is asked after the DR. The 24-hour DR data plus the corresponding dietary supplement intake are used to estimate total intake of foods and nutrients for the population. Additional questions related to diet are asked in the household questionnaire (Dietary Behavior and Nutrition section (DBQ), and Consumer Behavior section (CBQ)) and in the Flexible Consumer Behavior Survey (FCBS) module telephone follow-up interview.

d. Obesity , Growth and Development and Osteoporosis

Body Measures

Obesity is a major epidemic in children and adults, with nearly one-third obese. Obesity is associated with increased mortality and numerous health conditions. Anthropometric (body measurement) information are used to assess the growth and development of U.S. children, to estimate the prevalence of overweight and obesity, and to examine the associations between body measurements and lifestyle, health conditions and risk factors such as cardiovascular disease, diabetes, hypertension, physical activity, and diet. In addition to the body measurement examination results, NHANES will continue to collect self-reported information on maximum adult height and weight history during the household interview.

Osteoporosis

As the U.S. population ages, it is expected that the risk of hip fractures, the most costly fractures in terms of morbidity, mortality and health care costs, will increase. Femur (hip) bone mineral density (BMD) data will be used to track trends in osteoporosis in the adult population since NHANES III, as called for by Objective 2.9 of Healthy People 2010. Data from this component will also enhance the evaluation of skeletal health in the U.S. population by providing: a) estimates of osteoporosis at the spine; b) nationally representative data on spine BMD for ages 8 years and older; and c) nationally representative data on femur BMD in individuals ages 8-19 years. Femur BMD and questionnaire fracture history information will be used in a risk assessment model to assess absolute fracture risk. The model will be developed by a committee of the National Osteoporosis Foundation and International Osteoporosis Foundation. Osteoporosis is determined through BMD measurements obtained from dual-energy x-ray absorptiometry (DXA). Scans of the proximal femur and anteroposterior (AP) spine are administered to survey participants ages 8 years and older.

e. Oral Health (major modifications)

The Oral Health component methods used in 2005-2008 have been discontinued. The oral health exam for those 4 years had a target age group of 5 years and older. The protocol, known as Basic Screening Examination (BSE), did not assess each tooth surface and the assessments are not made by a dentist. NHANES use this simplified screening process to collect information on untreated caries, dental restorations, and dental sealants. In addition to performing the BSE the examiner inquired about the use of dentures, performed a tooth count, and ascertained the number of dental contacts.

The 2009-2010 oral health component uses a completely different methodology, described below. The target age group remains ages 5 and older. The specific assessment a participant receives is dependent on their age. NHANES will use a simplified screening process to collect information on tooth retention and loss, untreated caries, dental restorations, and dental sealants. NHANES will be evaluating for dental fluorosis on the upper six anterior teeth using protocols similar to 2003-2004. NHANES will also be adding a full-mouth periodontal assessment for 2009-2010. Data for this component will be collected using a visual-tactile examination. The oral health exam will be conducted by registered dental hygienists. Data will be recorded by a separate dental recorder.

Additionally, a rinsed specimen will be obtained to test for oral Human Papilloma Virus (HPV)

infection. Molecular evidence supports a role for HPV, particularly HPV-16, in the pathogenesis of a subgroup of squamous-cell carcinoma of the head and neck. Epidemiologic evidence of the role of HPV in squamous-cell carcinomas of the head and neck is less rigorous. Studies are underway to evaluate the natural history of oral HPV infection and its potential health consequences. NHANES will provide information on the prevalence of oral HPV infection in the general population

f. Respiratory Function

Spirometry Measurement

Spirometry is the measurement of exhaled lung volumes and expiratory airflow rates. It is a standard lung function test in medical practice and is used to define cases of clinical lung disease such as asthma and Chronic Obstructive Pulmonary Disease (COPD). Spirometric measurements of lung function, especially the Forced Vital Capacity (FVC), Forced Expiratory Volume in one second (FEV1), and their ratio (the FEV1/FVC %) are important for characterization of asthma and obstructive airway disease both for clinical as well as epidemiological purposes.

Spirometry will be performed the same way as in the 2007-2008 NHANES. The eligible age range is 6-79 years. Children and adults with airway obstruction detected by baseline pulmonary function testing undergo repeat spirometry after inhalation of a short-acting  $\beta_2$ -adrenergic bronchodilator. Bronchodilator reversibility spirometry testing is a standard clinical procedure and has been employed in many population-based surveys of asthma and COPD both in adults and children. Bronchodilator reversibility testing is used to distinguish more precisely between asthma and COPD and other causes of fixed obstructive lung disease, and is used to determine asthma severity and the degree of asthma treatment control. The NHANES spirometric testing protocol for baseline spirometry and bronchodilator testing meets current American Thoracic Society (ATS) Guidelines for quality control.

Exhaled Nitric Oxide (ENO) Measurement

Airway inflammation, a precursor of asthma symptoms, is important to the investigation of underlying respiratory disease. ENO, measured in exhaled breath samples, is a noninvasive marker of airway inflammation. Nitric Oxide (NO) is normally produced and detected in the exhaled breath from the respiratory tract where it plays important regulatory functions. NO concentrations increase following exposures to allergens. There appear to be large differences in ENO concentrations between asthmatics and healthy controls, and ENO may allow detection of cases of mild or incipient asthma which are usually symptom-free. NHANES is therefore conducting ENO testing data to complement its spirometric studies.

g. Inflammatory Back Pain/Spondyloarthritis Component (New):

The new Inflammatory Back Pain & Spondyloarthritis (SpA) Component will provide the first national-level data to define the population burden of the third most common type of arthritis among US adults. This task becomes more urgent with the recent discovery that biologic chemotherapy can dramatically improve the course of the disease. The purpose of this project is to screen for the prevalence of inflammatory back pain by questionnaire in U.S. adults 20-69 years of age, then to define the prevalence of Spondyloarthritis by clinical criteria using validated physical examination measurements to screen for limitations of spinal mobility; and HLA B27 blood typing.

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The age eligibility will be survey participants 20 to 69 years, the most common ages that inflammatory back pain and SpA occur. The arthritis questionnaire will be administered to participants in the NHANES household interview, and is based on previous clinical instruments used in clinical Rheumatology. In the MEC Examination, three previously validated physical body measurements will be obtained as an addition to the currently existing NHANES Mobile Examination Center (MEC) Examination Body Measures Component. These are the modified Schöber Test measuring lumbar spine flexion; chest circumference measurement with inspiration to measure thoracic spine mobility, and the Occiput-to-Wall Distance which measures cervical spine mobility.

Laboratory testing for the NHANES Spondyloarthritis Component consists of HLA B27 testing. HLA B27 is a human histocompatibility locus marker which has been utilized as a standard clinical diagnostic test for many years to assist in the diagnosis of SpA. This result will be reported to the survey participant as either a positive or negative result. HLA B-27 subtyping analysis will be performed, but subtype results will not be reported to survey respondents (at this point these are primarily research tests, and their epidemiologic significance is uncertain).

### h. Sensory Performance

#### Audiometry (Hearing) (Modified)

In 2009-2010 NHANES will cycle back in the hearing test for participants 70 and older (last done is 2005-2006), and continue hearing testing for those 12-19. The expected low prevalence in teenagers requires continued years of data collection to obtain reliable prevalence estimates. Additional data is also needed for U.S. adults 70+ years to provide more recent prevalence estimates. The hearing component was dropped from NHANES 2007-2008 for participants 70+ years to keep examination times for this age group, within the four hour total MEC session time. Since the vision and ophthalmology examinations are being discontinued in 2009-2010, there should be enough time for older adults to complete the hearing test.

The specific aims of this component are: 1) to update surveillance prevalence estimates of hearing loss in U.S. children and adolescents and among older adults; and 2) to evaluate certain covariates such as noise exposure and ear infections that may cause hearing loss in the 12-19 year age group and among older adults as well. The hearing loss data for older adults is also essential for estimating functional impairments and disability in this subpopulation. These data are central to developing and implementing national hearing loss programs. This component addresses the key Healthy People 2010 goal of reducing noise-induced hearing loss in children. 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.

#### NHANES Laboratory Assessments

This section describes environmental exposure, infectious disease and immunization status, nutrition related measures, biologic specimen banking project activities and other laboratory tests. In 2009-10 two additional items of information will be collected related to the urine collection in the MEC—urine osmolality and the urine flow rate (a.) Within environmental chemical exposure (b.) 3 new classes of chemicals have been added: methylnaphthalenes, polycyclic aromatic hydrocarbon(PAH) hemoglobin adducts, and ethylene oxide. Within some

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categories of environmental chemicals specific analytes have changed (b.) These are noted on the table in Attachment 8B. Other new laboratory tests for 2009 are human lymphocyte antigen B27 (HLA\_B27), antihuman recombinant-tissue transglutaminase (TTG) and endomysial antibody (EMA), measles, mumps, rubella, and varicella (MMRV), and human papillomavirus (HPV) oral rinse.

### a. Urine assessments.

#### Urine Osmolality

Urine osmolality measures the amount of solute particles contained in urine. It can indicate if the urine is overly diluted or concentrated due to hydration status or impaired renal function. Urine osmolality will be measured on participants ages 6+ years. The concentration of urine analytes (such as environmental chemicals) can fluctuate in spot (single determination) urine specimens depending on whether the urine is too diluted or concentrated. To compensate, the urine analyte concentration is divided by the urine osmolality to “standardize” the spot urine analyte concentration. Urine osmolality will be measured by freezing point osmometers in the Mobile Exam Center.

#### Urine Flow Rate

Urine analyte concentrations from single determinations (spot urines) are used to determine the exposure to environmental chemicals, however they can vary depending on the water content of the urine. The urine excretion rate of an analyte is a more accurate measure of the exposure to environmental chemicals. The urine excretion rate (mg/min) is the product of the urine flow rate (mL/min) and the urine analyte concentration (mg/mL). Participants ages 6+ will be asked to record their time of last void before coming to the Mobile Examination Center and then asked to void in the Mobile Examination Center where the time of collection and volume of the urine will be recorded and a urine flow rate will be calculated.

### b. Environmental Chemical Exposures

The NHANES environmental health component was expanded in 1999 in collaboration with laboratories of the National Center for Environmental Health (NCEH). It now includes approximately 150 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 Third National Report on Human Exposure to Environmental Chemicals (URL: <http://www.cdc.gov/exposurereport/3rd/default.htm>)

CDC/NCEH sought public comment on its proposed criteria for selecting environmental chemicals or categories of chemicals, and for adding and removing chemicals in future releases of the National Report on Human Exposure to Environmental Chemicals by placing notices in the Federal Register (Vol. 73, No. 61, March 28, 2008, pages 16685-8; Vol. 71, No. 94, May 16, 2006, pages 28346-7; Vol. 68, No. 189, Sept. 30, 2003, pages 56296-8; Vol. 67, No. 194, Oct. 7, 2002, pages 62477-8; Vol. 67, No. 54, Mar. 20, 2002, pages 12996-7). The NCEH laboratories continue to develop laboratory methods that will expand the list of environmental chemicals that can be measured through NHANES. Within classes of chemicals, analytes new in 2009 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.

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Note that selected categories of environmental chemicals are now proposed to be analyzed using pooled specimens (see Attachment 8B). Two considerations have motivated this change in protocol. One is the expense of measuring the compounds in hundreds of subjects. The second is related to the high proportion of results below the limit of detection (LOD) for some chemicals. One example is the polychlorinated dibenzo-p-dioxins and dibenzofurans. For many of these compounds, results for 90% or more of individual samples are below the LOD.

The environmental analytes include the following classes of chemicals:

- Cotinine
- 4-(Methylnitrosamino)-1-(3-pyridyl)-1-Butanol (NNAL)
- Heavy metals
- Mercury
- Phthalates
- Phytoestrogens
- Polycyclic aromatic hydrocarbons (PAHs)
- Organophosphate insecticides: dialky phosphate metabolites
- Organophosphate insecticides: specific metabolites
- Pyrethroid pesticides
- Organochlorine pesticides
- Other pesticides and fungicides
- Herbicides
- Halogenated phenolic compounds
- Perfluorinated compounds
- Polychlorinated and polybrominated dibenzo-p-dioxins and dibenzofurans
- Polychlorinated biphenyls (PCBs)
- Polybrominated diphenyl ethers
- Toxaphenes
- Volatile organic compounds in blood and water
- Acrylamide
- Perchlorate, iodide, and nitrate in water
- Perchlorate in urine
- Polychlorinated naphthalenes
- Parabens
- Methyl-naphthalenes (New)
- Polycyclic aromatic hydrocarbon (PAH) hemoglobin adducts (New)
- Ethylene oxide (New)

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, determination of 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

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- to observe time trends in the levels of exposure within the population
- to set priorities for human health effects research

Additional information on the classes of environmental chemicals is described as follows:

### Environmental tobacco smoke exposure

Cotinine: Cotinine, a metabolite of nicotine, is measured in the blood as a biochemical marker to substantiate self-report of smoking and to define exposure to environmental tobacco smoke (ETS). The harmful effects of cigarette smoking have long been established, and evidence has accumulated linking exposure to ETS with lung cancer, respiratory and other chronic diseases. Measurements of cotinine have been included in the survey since NHANES III. At that time, findings from NHANES showed a preponderance of exposure to ETS. While major efforts have been made to limit tobacco smoking in public places and restaurants in order to minimize ETS exposure, the inclusion of this biochemical marker is useful to examine trends and track progress in this area.

NNAL: Another tobacco biomarker of importance is NNAL, a tobacco-specific nitrosamine (TSNA) which is a metabolite of NNK (NNK is (4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone)) in the body, and which has been detected in the urine of smokers, and in many cases, in nonsmokers exposed to Second Hand Smoke (SHS). NNK is formed in tobacco and in cigarette smoke from nicotine, so it and its NNAL metabolite are as specific for tobacco and cigarette smoke exposure as is cotinine or nicotine itself. Furthermore, both NNK and NNAL are known to be potent pulmonary carcinogens in rodents, and they are believed to be lung carcinogens in people as well. Thus, measuring NNAL in people will help to address the exposures of both smokers and nonsmokers to this potent carcinogen.

Total NNAL in urine samples from NHANES 2009-2010 will be measured to help characterize the concentration levels of this important marker in the U.S. population of both smokers and nonsmokers, and to compare the findings with previous estimates based on a currently proposed retrospective assessment of residual samples from the NHANES 2005-2006 survey. As tobacco processing and cigarette manufacturing continue to change, and as newer tobacco delivery devices such as the “potentially reduced exposure products (PREPS)” are introduced, changes in carcinogen levels such as the TSNA may occur in people. Thus, we expect to continue to monitor NNAL in subsequent NHANES to track exposure levels in both smokers and nonsmokers over time. The use of surveys such as NHANES to address this issue has been implicitly proposed by the Institute of Medicine.

### Heavy metals

Trace metals were associated with adverse health effects in occupational studies or laboratory studies, but these substances have not been monitored in general population. Urinary antimony (Sb), barium (Ba), beryllium (Be), cadmium (Cd), cesium (Cs), cobalt (Co), lead (Pb), molybdenum (Mo), platinum (Pt), thallium (Tl), tungsten (W), and uranium (U) levels were measured in previous NHANES. Urinary assessments of chromium (Cr), manganese (Mn) and nickel (Ni) were added to the laboratory protocol in NHANES 2005-2006. Exposure information has been used to establish population-based reference ranges and to evaluate the need for regulations to reduce levels of exposure.

Mercury: NHANES 2009-2010 will continue to include measurements of mercury species (methyl, ethyl, and inorganic) in blood to define exposure to various sources of mercury more



precisely—methods became available for methyl and ethyl mercury and they are new to the protocol.

#### Pesticides and Other Chemicals

Phthalates: Phthalate acid esters (phthalates) are used extensively as plasticizers in a wide range of applications such as children's toys, food packaging, and medical supplies. Because some of these compounds are known to be estrogenic and have been associated with a host of health problems in rats, such as cancers and teratogenicity, governments in Europe and Japan have become increasingly concerned about levels in food packaging materials and children's toys. Biomeasures of phthalates in humans is necessary to evaluate potential human health threats from exposure to these chemicals.

Phytoestrogens: Many different plants produce compounds, called phytoestrogens that mimic or interact with estrogen. The major classes of phytoestrogens are lignans (present in flaxseed, carrots, berries, and grapes) and isoflavones (present in soybeans and other legumes). Biomeasures of phytoestrogens are necessary to establish reference ranges for these compounds and to evaluate their potential effects on human health.

Polycyclic Aromatic Hydrocarbons (PAHs) in Urine: PAHs constitute a group of chemicals which are formed during the incomplete combustion of coal, oil and gas, garbage, and other organic substances. These compounds require metabolic activation prior to their interactions with cellular macromolecules. PAHs are ubiquitous, thus exposure to them is widespread. In general, people are exposed to mixtures of PAHs, the sources of which include vehicle exhausts, asphalt roads, coal, coal tar, wild fires, agricultural burning, charbroiled foods, and hazardous waste sites. Although most of the data regarding the carcinogenicity of these compounds comes from rats and mice, epidemiologic studies have shown increased mortality due to lung and bladder cancer in humans exposed to coke-oven emissions, roofing-tar emissions, and cigarette smoke. PAHs enter the body quickly and easily by all routes of exposure and are readily and predominantly metabolized to hydroxylated metabolites as well as glucuronide metabolites. These metabolites are excellent indicators of exposure to the parent PAHs.

Polycyclic aromatic hydrocarbon (PAH) hemoglobin adducts: (New) PAH exposure studies have generally been conducted via analytical methods utilizing HPLC/ fluorescence or GC/MS measurement of hydroxy-PAH metabolites in urine. These metabolites have a detection window of approximately 72 hours following exposure. PAH adducts with proteins, however, provide an extended window for analytical measurements because they integrate the biological effective dose over the lifetime of the protein. Protein adducts are considered potentially valuable biomarkers for assessment of PAH exposure, with a preponderance of studies using hemoglobin or serum albumin as target macromolecules.

Measurement of PAH hemoglobin adults in the NHANES 2009-10 will produce national estimates of exposure and identify subgroups of the population that have a higher exposure to PAHs.

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Non-persistent pesticides (organophosphate insecticides, pyrethroid pesticides, other pesticides and fungicides, and herbicides): In the 2009-10 NHANES analysis of many pesticides will be measured in plasma as well as in urine. Parent compounds are measured in plasma, whereas metabolites of pesticides are generally measured in urine. Many of these pesticides were originally planned to be measured in serum in NHANES 2003-2004. However, degradation of parent compounds occurred in serum and these measurements were not done at that time. Methods have now become available to measure the pesticides in plasma. Therefore, additional pesticide metabolites in urine are being added in 2009-2010, because of development of laboratory methods.

Persistent organochlorines (organochlorine pesticides, polychlorinated and polybrominated dibenzo-p-dioxins and dibenzofurans, and polychlorinated biphenyls (PCBs)): Organochlorines are diverse, synthetic chemicals that are persistent in the environment and tend to bioaccumulate. Most of these chemicals are banned in the U.S. Assessment of exposure to persistent organochlorines in a representative sample of the U.S. population is needed to determine current prevalence and level of exposure and the potential for human health threat from exposure to these chemicals.

Perfluorinated compounds: Organic fluorochemicals are used in multiple commercial applications including surfactants, lubricants, paints, polishes, food packaging, and fire-retarding foams. Recent scientific findings suggest that several perfluorinated surfactants, a group of these fluorochemicals, are ubiquitous contaminants found both in humans and animals worldwide. Polytetrafluorethylene (PTFE) has numerous uses in many industrial and consumer products, including coatings on textiles and carpet; uses in the automotive, mechanical, aerospace, chemical, electrical, medical, and building/construction industries; personal care products; and non-stick coatings on cookware. Polyvinylidene fluoride (PVDF) is used primarily in electrical/electronics, building/construction, and chemical processing industrial sectors.

Polybrominated diphenyl ethers (BDEs): Brominated flame retardants (BFRs) are heavily used as additive or reactive chemicals in polymers and textiles. Increasing levels of polybrominated diphenyl ethers (PBDE) have been observed in mothers' milk from Sweden, Germany and Norway. PBDE concentrations found in North Americans are considerably higher than those found in Europeans. There is an increasing usage of PBDEs worldwide and results of several studies indicating that concentrations in North American populations may be increasing.

Toxaphene: Toxaphene is a mixture of chemicals that was one of the most commonly used insecticides in the United States prior to 1982. It consists predominantly of polychlorinated camphenes that are lipophilic (dissolve well in lipids) and persist for years in the environment. EPA banned the use of toxaphene in the U.S. in 1990. In 1993, EPA banned the importation of food that contained toxaphene residues. Toxaphene is considered a probable human carcinogen by EPA and the National Toxicology Program.

Volatile organic compounds (blood): Additional volatile compounds are added in 2009-2010 because of laboratory method development. Exposure to volatile organic compounds (VOCs) is ubiquitous. Chronic exposure to extremely high levels of VOCs can lead to cancer and neurocognitive dysfunction. VOC exposure assessment will be expanded to include additional analytes of toxicological significance to include chemicals that are on priority toxicant or critical contaminant lists, and thus of toxicological concern. Hexane is a widely used solvent with neurotoxic properties. Acrylonitrile is a probable human carcinogen used widely in the polymer industry. Cis- and trans-1,3-dichloropropenes and 1,2-dibromoethane are widely used as soil fumigants resulting in unknown human exposure. Furan also became a VOC toxicant of interest

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on May 7, 2004 when FDA released extensive data showing levels of this potential human carcinogen in food products.

In addition to assessing levels of VOCs in blood, VOC levels will be measured in home tap water specimens provided by NHANES participants from a water sample collected by the interviewer during the household interview.

Acrylamide: In April 2002 the Swedish National Food Administration and researchers from Stockholm University announced their findings that acrylamide, a toxic and potentially cancer-causing chemical, is formed in high amounts in many types of food prepared/cooked at high temperatures. Because acrylamide is formed during the cooking process, specifically when producing French fries, potato chips and other fried products, intake of acrylamide through consumption of these foods can be high, thus exposing a large portion of the population to this chemical and putting them at risk of adverse health effects. Acrylamide is known to cause adverse health effects. Continuing to assess exposure to this chemical is especially important to properly assess the risks associated with the consumption of food containing high levels of acrylamide.

Perchlorate: Perchlorate is a polyatomic anion that can disrupt thyroid function by competitively inhibiting iodide uptake. Widespread use of perchlorate salts has led to widespread environmental contamination. Perchlorate is primarily produced as ammonium perchlorate for use as an oxidant in solid fuel propellants for rockets and missiles. Lesser amounts of perchlorate are used in matches, fireworks, and automotive airbags.

In addition to assessing levels of perchlorate in urine, perchlorate levels will be measured in home tap water specimens provided by NHANES participants. The specimens are collected by interviewers during the household interview.

Polychlorinated naphthalenes (PCNs): Polychlorinated naphthalenes (PCNs) have been commercially produced and used mainly in electrical devices, but also for impregnation of wood, paper, and textiles to attain water-proofness, flame resistance, and protection against insects, molds, and fungi. Today, the PCNs are widespread in the environment and are regarded as an environmental problem. Generally, the levels are lower compared to polychlorinated biphenyls (PCBs), but high levels have been observed near point sources such as manufactures of chlorine/soda, magnesium, copper and aluminum. PCB products and incineration process are also sources of PCN releases.

Parabens: Parabens (alkyl esters of p-hydroxybenzoic acid) are a group of phenols widely used as antimicrobial preservatives in cosmetic products, pharmaceuticals, and food processing. Some parabens possess weak estrogenicity, although toxic effects of parabens in humans are mostly unknown. Human exposure to parabens may be assessed by measuring the conjugated or free species of these compounds or their metabolites in urine. To understand the extent of exposure to parabens in the general US population, information on concentrations of these phenolic compounds in the non-occupationally exposed population is required.

Methylnaphthalenes: (New) Methylnaphthalene, which refers to a mixture of approximately two thirds 2-methylnaphthalene and one third 1-methylnaphthalene, is a natural component of crude oil and coal. Methylnaphthalene is also found in pyrolysis and combustion products such as cigarette and wood smoke, emissions from combustion engines, asphalt, coal and tar residues, and used oils. Mixtures containing 2-methylnaphthalene are used in the formulation of alkyl-naphthalenesulfonates, chlorinated naphthalenes, and hydronaphthalenes. Pure 2-

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methylnaphthalene is a component used in the manufacture of vitamin K and the insecticide carbaryl. Following exposure, methylnaphthalene undergoes oxidative metabolism in the liver to form more polar metabolites, which are excreted primarily in the urine. Metabolites include naphthoic acid, methylnaphthols (Me-NAP) and dihydrodiols.

Measurement of Me-NAPs, starting in 2009-10, is designed to produce national population estimates to assess the exposure to these chemicals using the NHANES survey. The proposed data will provide an important opportunity to identify potential subgroups of the general population at particular risk of exposure.

Ethylene oxide: (New) Propylene oxide (PO) is a basic chemical intermediate that is mainly used for the synthesis of propylene glycols and polyethers, primary components of polyurethane foam. Propylene oxide also has limited use as a fumigant for dried fruits, nuts, and spices, as a sterilant in the healthcare industry and occurs in car exhausts and cigarette smoke. The major source of human exposure to PO is inhalation of contaminated air at work places where the compound is used. PO is carcinogenic to rodents as shown in the studies of the United States National Toxicology.

In recent years methods have been established that allow the measurement of human exposure to propylene oxide. Historically, most exposure assessments are performed by measuring propylene oxide in the environment and only little is known about the actual exposure in humans, making it very difficult to assess people's risks and monitoring their exposure over time. Inclusion in NHANES will provide an important opportunity to identify potential subgroups of the general population at particular risk of exposure.

### c. Infectious Disease and Immunization Status Assessments

Collection of the venipuncture specimen in NHANES provides an opportunity to assess previous infection or immunity to vaccine preventable diseases. Measurements of hepatitis E, and immunity to measles, mumps, rubella, and varicella (MMRV) will be added to the protocol in 2009-10 (see below).

Chlamydia: Active infection with *Chlamydia trachomatis* can be evaluated in a urine specimen using Ligase Chain Reaction assays. Urine from examinees ages 14-39 will continue to be tested for *Chlamydia trachomatis* using ligase chain reaction assays. NHANES offers an opportunity to assess the prevalence of Chlamydial infection in the general population and to monitor trends in prevalence as prevention programs are established and expanded.

HPV (Oral HPV new): Current human papilloma virus (HPV) infection will continue to be evaluated via the collection of a vaginal swab to examine for DNA from specific high and low risk sub-types of HPV. Additionally, sera from individuals aged 14-59 years will be tested for antibody to HPV-16. Trends in HPV seroprevalence will be compared with data from the previous surveys and with trends in herpes simplex virus type 2 (HSV-2) seroprevalence. HPV vaccine was approved in June 2006 increasing the importance of continuing to monitor the prevalence of this infection.

As mentioned in A. 2, NHANES Examination Component, e, p.11, a rinsed specimen will be obtained to test for oral Human Papilloma Virus (HPV) infection. NHANES will provide information on the prevalence of oral HPV infection in the general population. This collection will be included in the Oral Health Pilot Test (B. 4, Pilot Testing for NHANES 2009-2010, p.15).

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Hepatitis (hepatitis E is new): Sera will be tested for hepatitis A (6 years and older); hepatitis B core antibody (6 years and older), hepatitis B surface antibody (an indicator of immunization with HBV vaccine, 2 years of age and older), hepatitis B surface antigen (6 years and older); hepatitis C enzyme immunoassay, with positives confirmed and HCV RNA (hepatitis C Virus RiboNucleic Acid) genotyping of positive specimens (6 years and older), hepatitis C genotyping (6 years and older) and hepatitis D. This information is helpful in defining the epidemiology of hepatitis C. The determination of HCV genotypes in NHANES will provide a nationally representative assessment of genotype distribution of circulating HCV genotypes and monitoring changes in this distribution over time will provide insight into epidemiologic patterns of HCV infection in the U.S. In addition, the efficacy of available treatments differs by genotype, and a representative picture of the nationwide distribution of HCV genotypes may provide a sense of what the expected impact of treatment might be. The addition of hepatitis E, for participants age 6 and above, is the only change in the protocol.

Herpes: Sera from NHANES subjects ages 14-49 will continue to be tested for antibody to Herpes simplex 1 and 2 (HSV-1/2) to continue to monitor the prevalence of HSV-1/2 infection in the U.S. HSV-2 is an index of sexually transmitted infections. In addition, questions about those sexual behaviors that are risk factors for sexually transmitted infections and that are the focus of major national HIV and sexually transmitted diseases risk reduction efforts are included in the MEC interview. The joint availability of sexually transmitted infection and risk factor data in a national sample on a periodic basis is a unique and invaluable resource for evaluation of national HIV/STD risk reduction efforts and for risk-based modeling of the frequency and trends of sexually transmitted infections.

HIV: Sera from examinees ages 18-59 will be tested for HIV. The estimated prevalence of human immunodeficiency virus (HIV) infection in the United States population is an important measure of the extent of the medical and financial burden the nation faces due to this virus. NHANES III data (1988-94) and the NHANES 1999-present data on HIV infection will serve as a baseline for monitoring the changes in the epidemic over time in the general population of the United States.

MMRV (New): Sera from examinees ages 6-49 will be tested for measles, mumps, rubella, and varicella, starting in 2009-10. The number of doses recommended for varicella, measles, and mumps has changed over the years, largely in response to outbreaks. It remains important to monitor the proportion of the US population susceptible to each of these diseases and to investigate demographic subgroups with higher susceptibility to help guide our national immunization policies. Additionally, most of immunity for measles, mumps and rubella was achieved through vaccination, with very little boosting from wild disease that makes serology monitoring essential. Varicella vaccination policies changed in 2006 from a routine 1-dose to a 2-dose program.

d. Nutritional Biochemistries, Hematologies and other nutrition related laboratory measures

NHANES data will be used to estimate deficiencies and toxicities of specific nutrients in the population and subgroups, to provide population reference data, and to estimate the contribution of diet, supplements, and other factors to serum levels of nutrients.

Complete blood counts, serum folate, RBC folate, standard biochemical profile, ferritin, lipids, transferrin receptor, vitamin B<sub>6</sub>, vitamin D, trans fatty acids, and omega-3 fatty acids will continue in 2009. Caffeine exposure will be added to the protocol in 2009.

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Caffeine: (New) Caffeine is a naturally occurring plant alkaloid primarily found in beverages such as coffee, tea, soft drinks, and to a lesser extent in foods such as cocoa. Long recognized as a central nervous system stimulant, caffeine is used both recreationally and medically as means to combat drowsiness and increase alertness. These effects are in large part responsible for the well-established widespread consumption of traditional caffeinated beverages such as coffee, and the more recent “energy drinks”. As a result, caffeine is believed to be the single-most widely consumed psychoactive substance in the world. Epidemiologic studies of caffeine as a risk factor in major chronic diseases such as bladder cancer, breast cancer, colon cancer, cardiovascular disease and various reproductive and perinatal outcomes have yielded inconsistent results.

In addition to providing a more reliable means of assessing caffeine exposure, the quantitation of caffeine and its metabolites in urine may also provide a means of assessing differences in metabolic activity. Caffeine is a preferred metabolic probe for assessing cytochrome P450 1A2 (CYP1A2), xanthine oxidase (XO) and N-acetyltransferase 2 (NAT2) enzyme activities, all of which are involved in the activation or detoxification of various xenobiotic compounds. Though this is normally performed with a caffeine challenge under controlled conditions, it has been demonstrated that dietary caffeine can be used as a means of assessing CYP1A2 activity in random samples. The ability to identify metabolic phenotypes would provide additional information about phenotypic differences that might have a bearing on other health parameters.

### e. Biologic Specimen Banking:

Serum, plasma and urine will continue to be stored for future research. Collection of a genetic specimen will continue in 2009.

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. With the present explosion of gene determinations associated with disease, the penetrance of susceptible genes in the population can only be determined from a representative sample such as NHANES. The additional data collected during the survey, both biochemical and questionnaire, provide phenotypic information that can be associated with these genes.

NCHS will solicit proposals for use of the stored specimens. A technical panel will review and approve all proposals. Proposals for performing genetic research will be evaluated by the NHANES Genetic Technical Panel. All uses of stored specimens are subject to review and approval by the NCHS Ethics Review Board and the NCHS Confidentiality Officer.

All unused serum from laboratories will be stored for potential additional analyses.

### f. Other laboratory

Celiac disease and HLA B27 are new in 2009.

Prostate Specific Antigen (PSA): Total and free and complexed serum PSA among men 40 years and older will continue to be measured.

Kidney function: NHANES will continue to collect urinary albumin and urinary creatinine to be used, along with the serum creatinine, to estimate the population of

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persons with chronic kidney disease. Starting in 2009 a second urine specimen will be collected by the participant after the examination to obtain a repeat measure of urinary albumin. The participant will be asked to collect the first void after awakening.

Liver function: NHANES' biochemistry profile will continue to provide some indication of liver function to be analyzed in concert with the hepatitis profile.

HLA B27 (New): Laboratory testing for the Spondyloarthritis Component consists of measurement of HLA B27. HLA B27 is a human histocompatibility locus marker which has been utilized as a standard clinical diagnostic test for many years to assist in the diagnosis of ankylosing spondylitis. In the symptomatic spinal arthritis patient population, it has a sensitivity of 90% and a specificity of 90%. The prevalence of axial spondyloarthritis will be estimated by analyzing associations of the Arthritis questionnaire data with the three measures of spinal mobility on the Anthropometry examination; and HLA B27 laboratory testing.

Celiac disease (New): Celiac disease is an intolerance to dietary glutens that has protean manifestations. In population surveys in other countries, it is found in about 0.5 to 1 percent of the population. It may well be as common in the United States, but has not been adequately examined. Advances in diagnostic testing now allow accurate disease prevalence estimates using two step serological testing--antihuman recombinant -Tissue transglutaminase (TTG) and endomysial antibody (EMA). This test is new in 2009-10.

C reactive protein (CRP):

CRP is used to correct the iron status measures which are affected by inflammation. It can also be used to measure the body's response to inflammation from chronic conditions, such as arthritis, and environmental exposures to agents such as tobacco. Testing for CRP will continue in 2009-10.

Thyroid profile:

The thyroid profile will continue to be used to assess thyroid function.

### The NHANES Interviews

The topics presented in this section are questionnaire data collected as standalone components or to complement one or more NHANES examination or laboratory components. The questions are asked in the home, the MEC, or after the MEC examination during a telephone interview.

There is one new section proposed as a standalone component—Reactions to Race Questionnaire. Inclusion of the reactions to race questions on the 2009-2010 cycle of NHANES may enhance understanding of how reactions to race/ethnicity (a manifestation of racism) impact the health of our nation, and may provide insight into the underlying causes of observed racial/ethnic health disparities. The questions proposed for inclusion on the 2009-2010 cycle of NHANES measure: Socially-assigned race or ethnicity (distinct from self-identified race and ethnicity), racial/ethnic consciousness, which reflects the racial climate at a given place and time, and perceived differential treatment based on race/ethnicity, both at work and when seeking health care and the experience of physical symptoms and of emotional upset as a result of perceived differential treatment by race/ethnicity. In the state based Behavioral Risk Factor Surveillance System surveys reported differences in self perceived health have been observed based on socially defined race/ethnicity. For

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example, Hispanics who report being perceived as white, have much higher rates of excellent and very good health status in contrast to Hispanics who report being perceived as Hispanic.

A list of questionnaire changes is presented first followed by more detailed descriptions of some subjects with a greater focus in NHANES. (A more detailed discussion is noted by a lower case letter after the number item.) If the questionnaire changes are primarily related to an examination component, that is noted after the item.

The following questionnaire sections have changes in 2009:

1. The FCBS phone follow-up interview questionnaire (a.)
2. The Food Security Questions (FSQ) have minor changes in wording and order to be consistent with National Academy of Science recommendations (b.)
3. Bowel Health (BHQ) – Five questions on diarrhea, constipation, and laxative use have been added (c.)
4. Early Childhood (ECQ) – Questions on whether the mother quit smoking during pregnancy, newborn care in a critical care unit, and attendance at Head Start were dropped.
5. Oral Health (OHQ) - Fifteen new questions have been added. All the 2007-2008 questions were dropped. (A, 2, NHANES Examination Component, f, p.11).
6. Blood Pressure (BPQ)— Three questions about blood pressure measurement at home will be added in 2009. A question about prehypertension will be dropped in 2009 as a single question and will be combined with the borderline hypertension question.
7. Audiometry (AUQ) -- Audiometry examination data will again be collected for participants ages 70 and above, therefore related questionnaire items will be administered again to this group. (A, 2, NHANES Examination Component, h, p.13)
8. Demographics (DMQ). Questions about foreign travel related to a previously discontinued component will be eliminated.
9. Medical Conditions list (MCQ). A question on psoriasis and psoriatic arthritis will be added in 2009 to support the spondylo -arthritis component in the MEC. Two questions about celiac disease will be added in 2009 to accompany the laboratory test on celiac disease. Two questions about missing school and work from injury, illness, and maternity will be dropped for 2009-2010 because those questions have rarely been used. The prostate antigen (PSA) test questions and history of prostate cancer among close blood relatives will be dropped for 2009-2010 since these questions have 4 years data and similar questions are in the physician Examination questions in the MEC.
10. Urologic Health and Kidney Disease(KIQ) (h.) Eight questions on lower urinary tract symptoms and benign prostatic hypertrophy were cycled out because there was no longer interest in collecting by the collaborator.
11. Dietary Behavior and Nutrition (DBQ). Questions on breastfeeding/childhood feeding practices will be revised in 2009 to be consistent with the 2006 National Immunization Survey (NIS) and to be more specific in measuring current CDC recommendations.
12. Sleep disorders (SLQ). Only 3 questions related to sleep will be retained.
13. Sexual Behavior (SXQ). The sexual behavior questions are being revamped in terms of the order and wording of the questions. These are being cognitively tested in the fall of 2008.



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### a. Flexible Consumer Behavior Survey (Modified)

The Flexible Consumer Behavior Survey (FCBS) module was developed in collaboration with the Economic Research Service (ERS) of the U.S. Department of Agriculture (USDA) and has been included in the NHANES since 2007.

For 2009-2010 data collection cycle, 10 new questions are proposed for inclusion in the NHANES to gather additional information in two subject areas: food labels and organic foods.

Use of food labels has been associated with good diet and health outcomes. It is important to understand the reasons why people use or don't use food labels to plan future public education program on the use of labels. The current FCBS module asks about individual's use of food labels. The newly proposed questions will be a follow up to the current food label questions and ask respondents why they do or don't use food labels. Because little is currently known on this subject, an open ended question will be used during the pilot testing. The results from the pilot study will be use to construct response categories for the main study.

Organic foods are gaining consumer acceptance and have made inroads into main stream supermarkets. It is important to have a more detailed understanding about the use of organic foods, especially among different food categories. Since October 2002, USDA has implemented the National Organic Standards. The labeling of products as "organic" is a vital part of establishing organics in the marketplace. Asking about organic standards will help identify respondents who are paying greater attention to food attributes, and who, as a result, may have distinct dietary patterns. Asking about having seen the USDA organic seal will be a useful indicator to help monitoring the awareness of regulations related to organic foods. Seven of the eight newly proposed organic food questions will be asked only of those saying they use organic foods on an existing FCBS question in the NHANES. The eighth questions is an assessment of the awareness of the USDA Organic Seal.

A pilot study, scheduled from June 11 through August 28, 2008, will evaluate adding these 10 new questions to the phone follow up element of the FCBS module in the NHANES. This pilot study was approved by OMB on February 8, 2008. Results from the pilot study will be used to assess and improve these new questions' validity, and determine the feasibility of inclusion in the NHANES.

### b. Food Security and Nutrition Program Participation

The 2009-2010 NHANES will continue to include a food security section (FSQ) that contains the 18-item U.S. Household Food Security Survey Module (US FSSM) and individually-referenced food security questions for respondents 12 and older.

Questions on Food Stamp and Program participation are also included in the FSQ section. Food stamp and household and child WIC data are collected in the family and Sample Person sections of the household interview; WIC data for women of childbearing age are collected in the reproductive health section of the MEC interview.

A feasibility/pilot test linking NHANES records to Food Stamp and WIC Program administrative records is planned for CY 2009 based on data from one state containing NHANES locations from NHANES 2007-8. If successful this may become part of the protocol for the NHANES 2009-2010 cycle of NHANES. A change request will be generated when a detailed protocol is developed.

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NHANES is the only nationally representative survey that collects information on food security at the household and individual level, as well as food program participation, physical health, and mental health. The data will be used to examine associations of household and individual-level food security with diet and health.

### c. Bowel Health and Pelvic Floor Disorders (Modified)

The bowel health component, introduced in 2005, is designed to produce national estimates of the prevalence of fecal incontinence and defecatory dysfunction in adult women 20 years and older. Sensory and emptying abnormalities of the lower gastrointestinal tract are among the symptoms for pelvic floor disorders. Pelvic floor disorders are a group of clinical conditions whose symptoms also include urinary incontinence, nocturia, and pelvic organ prolapse. The bowel health questions are also being asked of men 20 years and older to obtain national prevalence estimates of fecal incontinence and defecatory dysfunction in men.

### d. Dietary Supplement (DS) Use

NHANES continues to collection dietary supplement use information on all sample during the household interview. The information collected on DSs and antacids since 1999 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. In 2007-2008 NHANES added collection of a 24 hour supplement intake recall after both of the dietary recalls. Collecting dietary supplement data using the same methodology and time frame as the food data collection will allow us to combine these data and calculate total nutrient intake.

### e. Prescription Drug Use

NHANES continues to collect all prescription drug use during the past month. The duration of drug use and reason for use are also collected. Presently, NHANES collects information on all prescription medicines used by participants in the month prior to interview.

### f. Mental Health (Depression) (DPQ)

NHANES continues to collect a depression screener questionnaire on all respondents 12 years and older. One goal of this component will be to understand the co-morbidity of depression and other chronic diseases including cardiovascular disease, diabetes, and obesity. This information will be used to investigate other health risk factors related to depression in adolescents and adults. Depression is being assessed using the Patient Health Questionnaire (“PHQ-9”). This screening instrument has been validated against independent structured diagnostic interviews in both clinical and general population studies, and serves both as a depression severity measure as well as a diagnostic instrument for the Diagnostic and Statistical Manual of Mental Disorders, 4<sup>th</sup> edition (DSM-IV) depressive disorders. The PHQ-9 refers to the previous 2-week interval and consists of 9 items of depression symptoms plus a question on functional impairment

### g. Weight History and Weight Behavior

NHANES continues to collect data for all participants 8 and older related to weight history and selected weight related eating habits. Children and adolescents are especially prone to fad

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diets and eating disorders. Unhealthy methods of weight loss can compromise growth and are not recommended by health care professionals. Beginning in NHANES 2005 questions on the reasons for weight loss and the types of weight loss practices used by children and adolescents ages 8-15 years were added to the MEC CAPI interview. This information will be used with socio-demographic and related nutrition and health information to develop public policies and programs to prevent and manage overweight among children and adolescents.

The weight history component for adults is designed to permit evaluation of height loss with aging and patterns of weight status (stable, cyclical, maintained loss patterns) in adults.

### h. Urologic Health (Modified)

Self-reported information on urinary incontinence and nocturia, prostate cancer, and benign prostatic hypertrophy continue to be collected. These data will be 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. The urologic questions about prostate conditions will be used in concert with the prostate specific antigen (PSA) data collected for the laboratory component.

### i. Telephone interview of hepatitis C positive participants:

NHANES is the only population-based study from which prevalence data are available on hepatitis C infection. Hepatitis C virus (HCV) is the most common chronic blood borne infection in the U.S. Although there is currently no vaccine to prevent HCV transmission, there are clear recommendations for infected persons to reduce risks for transmitting HCV to others. In addition, there are important recommendations for infected persons to prevent further harm to their liver and to be medically evaluated for chronic liver disease and possible treatment. A telephone survey of NHANES participants who are anti-HCV positive has been conducted since 2001 to determine the proportion of individuals who already knew of their infection status, what they know about hepatitis C, and what actions they are taking following the report of findings letter that informed them of their infection status. Telephone follow-up interviews will continue in 2009.

### j. Other Interview Information

The NHANES interviews include questions that are included 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 (HUQ), Health Care Utilization (HCQ), and Occupation (OCQ) sections.

Additional questions are included in the Survey to assess such topics as reproductive health, risk behavior, and diet behavior in the U.S. population. Brief descriptions of the major NHANES supporting interview sections are provided and 2009 changes summarized.

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

Cigarette and Tobacco Use: Questionnaire items include use of cigarettes, pipes, cigars, smokeless tobacco and nicotine replacement products. Detailed information on past and

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present cigarette use including usual cigarette brand is asked of respondents 12 and older. Information on exposure to environmental tobacco smoke (ETS) at home and at work is also obtained. ETS exposure is assessed for examinees 3 years of age and older through the measurement of serum cotinine, a metabolite of nicotine.

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). Most of the data collected in this questionnaire section will be used as covariates for other analyses.

Sexual Behavior: (Modified) The information on sexual behavior is key to reducing the risk of STDs. Such behaviors include delaying onset of sexual intercourse by adolescents, minimizing number of sexual partners and utilizing barrier contraceptives. Sexual behavior, as well as other risky behaviors such as drug use was first included in NHANES III for use in analysis of serologic markers of sexual disease. 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.

A selected subset of these questions will be asked for participants ages 60-69. This will provide further information about risk factors in the aging cohort for infection with hepatitis C.

Drug Use: (Modified) 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. No measurements for the presence of drug metabolites will be conducted. 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.

For 2009 a selected subset of these questions will be asked for participants ages 60-69. This change was to provide further information about risk factors in the aging cohort for infection with hepatitis C.

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

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

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disseminates the information to survey collaborators, federal agencies, and NHANES data users.

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

The survey expects to continue conducting pilot studies for future cycles of continuous NHANES. During 2009-2010, pilot studies will be conducted to prepare for implementation during NHANES 2011-2012. Plans for future pilot studies have not been finalized.

All methodological and/or pilot studies would have a change package submitted to OMB before undertaking the study.

This request still permits NCHS the option to plan and conduct a Community HANES (C-HANES) project. C-HANES is a survey mechanism to address health status issues of defined populations (e.g., race/ethnic groups and/or small geographic areas) for which the standard, cross-sectional NHANES is inappropriate or infeasible. The age groups surveyed may be broad or may be restricted to certain subgroups, depending on the community's needs. C-HANES should provide rapid access to health data. Typically, the time elapsed from the start of a project to data dissemination will be less than two years. The C-HANES can also provide a means to bring an examination center to the sample person through the use of smaller mobile examination units than the MECs used in the main survey.

The C-HANES interview and examination components and their protocols will be similar to those of previous NHANES. However, new components and new data collection methods may be added depending on the objectives of the survey and the population surveyed. The data collection system will include some or all of the following: interviews in the home; interviews at the examination center; physiological, medical, and dental examinations; and biological specimen collection. Space, time, and resources will be, as usual, the limiting factors for what can be done in the survey and where.

CDC is including burden hours to accommodate a C-HANES project involving up to 4,000 participants (Section 12, Table 1, line 2). This project would include an interview and examination component similar to the current NHANES, but no post-examination components. Pilot tests or methodological studies to develop new NHANES components are also included in the line 2 burden. OMB would be notified of any such projects through a change package.

### 3. Use of Information Technology and Burden Reduction

The majority of NHANES data, approximately 95%, are collected from respondents electronically, which helps reduce burden.

NHANES uses survey information technology architecture (SITA) that supports fully automated and integrated information technology, relying on innovation and modern tools, and state of the art technology and information science. SITA provides increased capabilities that allow processing of complex data with significantly less editing than in previous NHANES surveys. The innovative design supports data changes in the survey requirements to reflect changing public interest and priorities. Most importantly, it allows NCHS to significantly reduce the cycle time to release data to the public.

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 all phases of the survey including: 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.

SITA was developed with the following general principles:

- Software/System Engineering Practices: SITA was planned, developed, and deployed utilizing the practices of a recognized software/system development methodology such as the Capability Maturity Model to insure quality, reliability, integrity, security, repeatable processes, thorough documentation, and decreased defects. SITA incorporates processes to insure the highest quality in the design and development, deployment, change management, and defect detection and rectification.
- Risk Management: SITA mitigates risk associated with development, integration, deployment, production, systems, and operations.
- Standards: SITA utilizes to the greatest extent possible national, international, and CDC and NCHS standards.
- Documentation: SITA lifecycle documentation is available on all aspects of the project lifecycle in electronic format.
- General Principles for Computer Applications and Systems: SITA relies on modern tools and technology for applications and systems. These systems are fault tolerant, flexible, interoperable, secure, stable, and allow for future development and changes.
- Data Collection Operational Units: SITA supports all operational units.
- Data Dissemination: SITA supports those functions needed to produce and disseminate datasets, metadata, reports, and analysis functionality in the most efficient manner and with the highest quality possible.

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Technologic innovations such as monitoring examination flow and the use of CAPI methods have allowed increased amounts of data to be collected during the same period compared to earlier surveys.

### 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. The organizations contacted are listed in Attachment 3 of this clearance request.

### 5. Impact on Small Businesses or Other Small Entities

Only individuals will be asked to participate.

### 6. Consequences of Collecting the Information Less Frequently

Prior to 1999, NHANES were conducted periodically. There was a twelve year interval between the starting dates of NHANES II and III and there was an 11 year interval between the beginning of NHANES III and the current NHANES. New data items could only be added at the start of a survey cycle. These long intervals created major gaps in data availability. In addition, they made it difficult to introduce new topic areas into NHANES because the demand for data on the most highly prevalent conditions became acute during the intervals between the periodic surveys.

Because data needs and health concerns change rapidly, policy makers need current information to plan and evaluate Healthy People objectives, prevention and treatment programs, and the impact of legislative reform. To address these needs, in 1999 NHANES began continuous data collection. This reduces the potential for gaps in objective data needed by epidemiologists, health care planners, public health officials, and health policy analysts to answer policy and research questions.

Nutrition monitoring legislation explicitly calls for continuous coverage to monitor nutrition changes as they occur (see Attachment 1). Major changes in the consumption of food can occur with the successful marketing of new products or products marketed with specific health claims. Continuous data collection will facilitate timely evaluation of these changes. Continuous data collection will permit more frequent updates of reference standards and more timely development of reference standards for new diagnostic procedures. Emerging and re-emerging health problems can be added to the content of NHANES more readily if data are being collected continuously. Continuous collection of objective data will permit more timely evaluation of Healthy People objectives that require this data. Continuous data collection allows for greater flexibility in addressing all the objectives of NHANES and coverage of more population subgroups. The objectives of NHANES support the need for the continuous collection of NHANES data.

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Respondents will participate in the data collection only one time. This may include follow-up studies. Three telephone interviews occur after the examination. Currently, there is a follow-up study involving a few hundred participants with positive hepatitis C tests. These participants are asked to complete a short telephone interview as described in Section B.2., Data Collection Procedures. A second dietary recall is obtained on all survey participants. Adult sample persons 16 years and older who completed the second dietary recall will receive the Flexible Consumer Behavior Survey (FCBS) phone follow-up interview. The FCBS phone interview data is collected at the family level for children ages 1-15 years old, that is, the data from the FCBS interview of one adult participant or proxy will be linked to all eligible children in the home.

Future NHANES activities may also include additional follow-up studies.

There are no legal obstacles to reducing the burden.

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

This data collection fully complies with the regulation.

### 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 July 3, 2008 (Volume 73, Number 129, page 38224). Attachment 2a contains a copy of the notice.

Four letters were received in response to the notice. They were from the National Fisheries Institute, General Mills, Friends of NCHS, and the Asian and Pacific Islander American Health Forum. All were supportive of continuation of the NHANES data collection. The four responses are included in Attachment 2b.

#### b. Outside Consultation

The content of NHANES is developed with input from numerous DHHS agencies (including NIH, FDA, and CDC), non-DHHS Federal agencies (including EPA, USDA, and HUD), non-government organizations, and individuals. The DHHS Data Council has been kept informed of the 2009-2010 NHANES plans. The DHHS Office of the Assistant Secretary for Planning and Evaluation has been briefed about the NHANES 2009-2010. Additionally, NCHS's Board of Scientific Counselors has been informed on future planning.

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 NHANES proposal guidelines are posted on the NHANES website.



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The major efforts taken to support collaboration processes are described below. Selected names, phone numbers, agencies, etc. for the collaborative activities can be found in Attachment 3.

New content proposals were solicited for the 2009-2010 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. Approximately 18 proposals were received in response to this solicitation. The responses ranged from a request to add one data item to requests to add complex examination components such as inflammatory back pain & spondyloarthritis, a revised oral health examination, and a dietary screener.

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 Gifts to Respondents

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

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

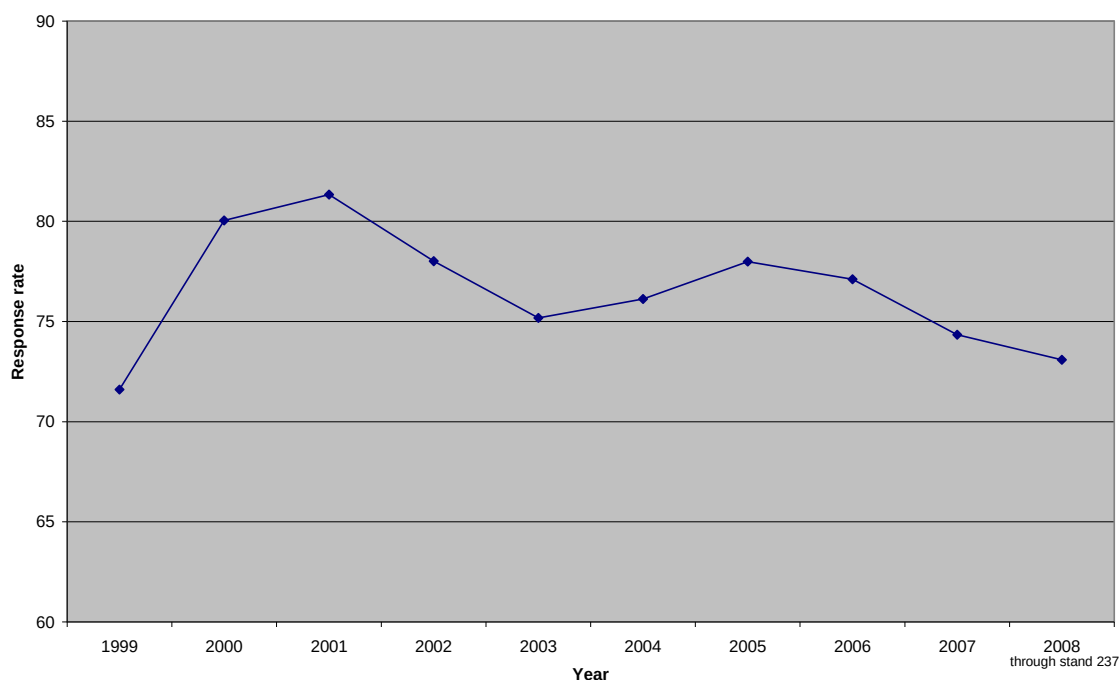
Continuous NHANES began in 1999 and the response rate was only 72%, therefore a remuneration study was undertaken in 2000. The basic comparison groups were the current level of remuneration plus a level approximately 50 percent higher. After 5900 observations the overall response rate in the higher versus lower paid group was 78% and 77%, respectively. The results varied by various characteristics of the respondents but the remuneration was not increased. Of particular relevance to 2009 is the fact that the response rate was 2.7% higher for the higher paid group, if the high income participants were excluded. Since the remuneration study, NHANES has begun oversampling the low income non-black non-Hispanic population.

Interviewers were not blinded to the remuneration and their primary objective is to get the participant to the examination center. Comments made during the debriefing suggested that interviewers spent more time convincing the lower remuneration group to be examined.

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Due to decreased response rates in NHANES 2007-2008, we would like to increase the remuneration for NHANES 2009-10 (See graph below of yearly examination response rates 1999-2008.). The interview and examination responses rate for 2007 and 2008 to date (May) are 74% and 73% respectively. The NHANES 2005-6 was 77%. In 2001, the response rate was at an all time high of 81%. We propose to increase the remuneration rates to adjust for inflation over the last 10 years rounded to the nearest \$5. An exception to this is the remuneration for the 12-15 year olds. From 1999-2001, this age group had the same remuneration as those 16 and older. While searching for cost savings in the operation of the survey, we decreased their remuneration to \$50 in 2002. Currently, participants ages 12-15 have an examination protocol as extensive as adults. Although we aren't proposing to increase the remuneration to the same level as adults, we are proposing a greater increase than just the inflation rate. Note: There are half as many adolescents in 2009-10 as there were in the survey when the remuneration was decreased.

SP Response Rates



We are not proposing an increase in the remuneration for the telephone interviews. The new post-examination component, a second urine collected at home and mailed back, is added to the 2009 protocol. We are proposing a \$40 remuneration for that collection. In 2002, we pilot tested two post-examination components that required the participant to mail something back. The first was a home completed food frequency questionnaire. We offered differential remuneration during the pilot. Of the 316 participants contacted for the pilot, who were told that they would receive \$20, 71% returned forms. Of the 354 cases that were told they would receive \$30, 77% returned forms.

The second pilot involved receiving a physical activity monitor (PAM) at the MEC and mailing it back after wearing it. In 2002, during the pilot for the PAM, DHANES remunerated \$30. The response rate during the pilot test was 67%. We concluded that an increase in remuneration would likely increase the response rate. We remunerated \$40 from 2003-6 and the response

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rate was 92%. We feel strongly that the \$40 remuneration contributed to this high response rate. The PAM component is similar in complexity and burden to the second urine collect and a similar remuneration should maximize the response rate.

Below are the current and proposed payment rates.

**Examination payment**

Subgroup	1999-2008 Payment	2009-10 Payment
16 and older correct session	\$100	\$125
16 and older incorrect session	\$70	\$90
12-15 correct session	\$50	\$90
12-15 incorrect session	\$30	\$60
Under 12	\$30	\$40

**Post-primary examination payment**

Dietary Phone Follow Up	-	\$30
Flexible Consumer Behavior Survey (FCBS)		\$15
Urine albumin/creatinine ratio collection in the home		\$40

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 to be examined in the MEC, they are reimbursed at \$5.25 an hour up to 6 hours. Participants also receive a transportation allowance for driving to the MEC, or a taxi is provided. (As of 7/17/2008 these amount were not increased to reflect the recent increases in fuel costs.)

**SP transportation allowance**

Mileage to MEC	Current Plan	
	Cities	Rural Areas
<16 Miles	\$ 30	\$ 25
16 – 30 Miles	\$ 45	\$ 40
31 – 59 Miles	\$ 55	\$ 50
>59 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). Over the last 2 years we have increased our efforts to recruit more experienced interviewing staff, increased the training and retraining time for obtaining respondent cooperation and refusal conversion techniques, and trained field supervisory staff on more one-on-one mentoring of interviewers on non-response conversion techniques. At each stage of contact with a PSU we have increased our attention on activities to reduce nonresponse. The PSU address listers must note every locked building, gated community, and college campus during their visit 4 months before field operations and notify the field operations team. The NCHS advance visit to PSUs has increased the emphasis on building community support during their pre-data

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collection visit. We have increased training of field office staff on appointment reminder calls and dealing with participants who call with questions and concerns. We've increased our efforts to get local media coverage and local endorsements.

We have not increased the number of interviewing staff. It has remained the same since 1980. Because the NHANES field staff travel full time, hiring more interviewers is a costly option to try to increase response rates. Our contractor finds it a constant challenge to recruit and retrain high performing interviewers who are willing to travel full time, so in addition to the high cost of interviewers, it may not be possible to maintain a larger interviewer staff.

### 10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974 (5 U.S.C. 552a) "requires the safeguarding of individuals", and Section 308(d) of the Public Health Service Act (42 U.S.C. 242m) requires the safeguarding of both individuals and establishments against invasion of privacy. Contractors who collect information identifying individuals and/or establishments must stipulate the appropriate safeguards to be taken regarding such information. The Privacy Act also provides for the confidential treatment of records of individuals, which are maintained by a Federal agency according to either individual's name or some other identifier. This law also requires that such records in NCHS are to be protected from "uses other than those purposes for which they were collected."

The 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").

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

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information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than 5 years, or fined not more than \$250,000, or both.”

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

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

It is the responsibility of all employees of NCHS, including NCHS contract staff, to protect and preserve all NHANES data (this includes all oral or recorded information in any form or medium) from unauthorized persons and uses. All NCHS employees as well as all contract staff have received appropriate training and made a commitment to assure confidentiality and have signed a “Nondisclosure Affidavit”. Staffs of collaborating agencies are also required to sign this statement and agencies may be required to enter into a formal agreement with NCHS before access to 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.

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. Justifications for Sensitive Questions

Objective data of a sensitive nature are described in this section. Content of a sensitive nature in the examination is discussed in the NHANES informed consent document (Attachment 5).

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### a. Social Security Number

Social Security Number (SSN) of all participants, children through adults, is requested in the household interview as a key item. The information is used to link administrative and vital records, such as the National Death Index (NDI), to the survey information. Additionally, in 2009-2010 NHANES will use the SSN to link with Food Stamp Program and Women, Infants and Children Program administrative records from the USDA.

Permission to link is obtained from respondents as follows:

“The Department of Health and Human Services 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 Department will not release it to anyone, including any government agency, for any other reason. Providing this information is voluntary and is collected under the authority of Section 306 of the Public Health Service Act. There will be no effect on {your/his/her} benefits if you do not provide it.”

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

### b. CMS Health Insurance Claim Number

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

Permission to link is obtained from respondents as follows: “This number is needed to allow Medicare records of the Centers for Medicare and Medicaid Services (CMS) 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. Except for these purposes, the Department of Health and Human Services will not release your Health Insurance Claim Number to anyone, including any other government agency. Providing the Health Insurance Claim Number is voluntary and collected under the authority of the Public Health Service Act. Whether the number is given or not, there will be no effect on your benefits. This number will be held in strict confidence. [The Public Health Service Act is 42 USC 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

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their participation in the survey or any of its components. Again during the physical examination, each sample person is reminded that he or she can refuse to answer questions or undergo any parts of the examination that are objectionable.

All questions and procedures are being reviewed by the NCHS Ethics Review Board (formerly called the NCHS Institutional Review Board) and the data collection contractor's institutional review board for issues of sensitivity and safety (see Attachment 6). The potential sensitivity of questions and procedures is an evaluation criterion in determining content of the survey. The multipurpose nature of NHANES makes it necessary to exclude topics so sensitive that they may interfere with participation.

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

- 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, chlamydia and selected strains of 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 both self-reported information on sexual behavior and the objective data on infection.

The questions on sexual behavior were developed in consultation with other centers of CDC and are similar to those developed by the National Survey on Drug Use and Health (OMB 0930-0110), National Survey of Family Growth (NSFG)(OMB 0920-0314) and those used in NHANES III. These questions will be administered using A-CASI methods in a private room.

Questions on sexual activity are asked of males and females 14 years and older. It is important to ask these sensitive questions because many teenagers are sexually active and because sexual activity is a risk factor for disease transmission. The National Survey of Family Growth reported that in 2002, 46 percent of never-married teen females had experienced sexual intercourse at least once. In 2002, about the same percentage of never-married teen males were sexually experienced as were females: 46 percent. NHANES is the only national health survey that assesses sexually transmitted disease exposure and prevalence in U.S. youth and adults using biologic specimens. 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.

- 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. Similar questions were asked in NHANES III. The MEC interview is conducted in a private room. Illicit drug use, tobacco, and alcohol questions are administered to youth 12-19 years of age in A-CASI mode.
- iii. Reproductive health and menstruation: Questions on reproductive health history and use of oral contraceptives, asked of females 12 years and older, may be considered sensitive by some respondents. Privacy is assured by asking the questions in the MEC interview room.

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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, and will be self-reported for all females 12 years and older. 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. This will be explicitly addressed in the informed consent document.

- 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 with full confidentiality in a private room in the mobile examination center by specially trained interviewers. Participants will also be told that they may terminate the interview at any time. No matter when the interview is terminated, the interviewer will try to help the participant leave the setting with positive feelings about his/her willingness to take part in the interview.

A report of findings referral system will be in place at the MEC for immediate referral for those whose results indicate depression.

- v. Male and female urologic health: Conditions such as urinary incontinence, prostate hypertrophy, prostate cancer, 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 with full confidentiality in a private room in the mobile examination center by specially trained interviewers. Participants will also be told that they may terminate the interview at any time.
- vi. Bowel health: The information collected in NHANES is critical to understanding the magnitude of fecal incontinence and defecatory dysfunction and their impact on health and quality of life. The interviews will be conducted with full confidentiality in a private room in the mobile examination center by trained interviewers. Participants will also be told that they may terminate the interview at any time.
- vii. Vaginal Swabs: Women ages 14-59 years will be requested to collect a self-obtained vaginal swab. The swab will be used to test for human papilloma virus (HPV). Survey participants will perform the swab collection in a private bathroom.
- viii. Reactions to Race: Respondents 18 years and older will be asked to complete a self-administered questionnaire about how they perceive they have been treated in health care and work settings, based on their race/ethnicity. They will also answer questions about whether or not their health has been impacted by this perceived treatment. The questions will be answered in a private room in the mobile examination center using Audio Assisted Computer Self-Interviewing (ACASI)
- ix. Future content: As discussed in the Responding to Emerging Public Health Issues, New Technology and Future Survey Options portion of section A.2., during the conduct of 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



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will be explicitly discussed in the informed consent document if the content is considered sensitive, and appropriate privacy and confidentiality safeguards included.

### 12. Estimates of Annualized Burden Hours and Costs

#### a. Time Estimates

This submission requests OMB approval for three years of data collection, specifically for the 2009-2010 NHANES and for testing modules for the 2011-2012 survey. These data collections will occur within the context of ongoing NHANES data collection activities. The burden for each survey component of one complete survey cycle is shown in the table below. The estimated total burden for one year is 49,626 hours, including screening, examination, follow up interviews, tests of procedures and special studies.

Annually, approximately 18,813 respondents participate in some aspect of the full survey (Attachment 9). Of these about 70% (Over 13,000 respondents) complete the screening portion and are then screened out of the sample. Approximately 300 additional respondents complete the screener and the household interview sections, but decline to be examined. The remaining 5,180 participate in the screener, household interview and physical examination. The majority of these people also participate in one or both of two follow-up telephone components -- the second dietary recall interview and the Flexible Consumer Behavior Survey (FCBS). A very small number participate in a hepatitis C follow-up. Averaging the burden across all respondents, at these varying levels of participation, results in an average burden of 2 hours. (The respondents who participate in all aspects of the survey can expect an estimated burden of 6.7 hours as documented in the signed informed consent documents [attachment 5].)

Up to 4,000 additional persons (non-NHANES respondents) might participate in tests of procedures, special studies, or a Community HANES, if budgeted. The average burden for these special study/pretest respondents is 3 hours (Attachment 11).

**TABLE 1 – ANNUALIZED BURDEN HOURS AND COSTS**

Type of Respondent	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)	Total Burden Hours
1. NHANES Respondents	18,813	1	2	37,626
2. Special study/pretest participants	4,000	1	3	12,000
<b>Total</b>				<b>49,626</b>

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b. Cost to Respondents

The hourly wage rate of \$17.95 per person is based on income from wages and salary from the BLS Employment Situation Summary Table A of average hourly earnings, May 2008. This wage rate for all persons was used since respondents do not fall into a single economic or occupational category. The total cost was \$890,787 or \$39.05 per respondent. (NOTE: There are no out-of-pocket costs to survey participants. Participants are remunerated for their time as well as for child care and transportation expenses.)

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

None.

14. Annualized Cost to the Federal Government

This project is a multi-year, continuous survey, with survey planning, data processing and analysis, and data collection occurring simultaneously. These figures are broad estimates based on past NHANES data collection budget estimates. Various analyses on the laboratory component (Attachment 8) are also in the process of having contracts awarded. Staff costs were primarily based on Division of Health and Nutrition Examination Surveys personnel costs, which were obtained from the NCHS Financial Management Office. A proportion of these costs are paid by funds transferred to the CDC budget from collaborating agencies. Estimated funds from agencies outside of CDC are summarized below. More precise figures of support from other agencies will be available in FY 2009.

Table 1. Estimated survey cost per year

Category	Annualized Cost
Equipment, exam centers, data collection and processing, contracts, labs/readings	\$35,000,000
NCHS staff costs for survey planning, data analysis and overhead	\$6,000,000
NCHS printing, travel, supplies, etc. for NHANES staff	\$350,000
Total	\$41,350,000

Table 2. Anticipated survey support from outside NCHS\*

Agency (component)	FY2009	FY2010
CDC, NCCDPHP, DOH (Oral Health)	545,000	545,000
CDC, NCCDPHP, DDT (Diabetes)	400,000	400,000
CDC, NCCDPHP, DDT (Ophthalmology)	445,000	0

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CDC, NCCDPHP, DACH (Quality of Life)	325,000	325,000
CDC, NCCDPHP, OSH (Smoking & Health)	260,000	260,000
CDC, NCCDPHP, DCPC (PSA Testing)	305,000	305,000
CDC, NCCDPHP, DNPA (Nutrition)	297,000	297,000
CDC, NCHSTP, DSTDP (Sexual Behavior)	518,000	518,000
CDC, NCID, DVHP (Hepatitis)	330,000	330,000
CDC, NCBDDD, DBDDD (Folate)	150,000	150,000
CDC, NCCDPHP, DACH (Reactions to Race)	160,000	160,000
CDC, NCCDPHP, DDT (Kidney Function)	385,000	385,000
CDC, NCEH, DLS (Nutritional Biochemistry and Environmental Exposures)	1,640,000	1,640,000
USDA, ERS (Food Security)	160,000	160,000
USDA, ERS (Consumer Behavior Survey)	1,125,000	1,125,000
FDA, CFSAN (Nutrition Assessment)	250,000	250,000
EPA, OPPTS (Dietary Recall)	300,000	300,000
NIH, NCI ( Food Frequency)	300,000	300,000
NIH, NICHD (Incontinence)	175,000	175,000
NIH, NHLBI (Cardiovascular and Respiratory Disease)	2,290,000	2,290,000
NIH, NIAMS (Arthritis)	600,000	600,000
NIH, NIAMS (Osteoporosis)	360,000	360,000
NIH, NIDCD – (Hearing)	260,000	260,000
NIH, NIDDK – (Diabetes)	430,000	430,000
NIH, NIDDK – (Kidney)	625,000	625,000
NIH, NIDDK (Celiac Disease)	340,000	340,000
NIH, ODS (Dietary Supplements and Nutritional Biochemistries)	1,000,000	1,000,000
USDA-ARS-(24-hr dietary recall)	2,480,000	2,480,000
TOTAL	16,455,000	16,010,000

\*Balance of the estimated survey cost per year in Table 1 is from NCHS budget

15. Explanation for Program Changes or Adjustments

The current approved annual burden hours are 59,864. We are now requesting approval for 49,626 hours, a decrease of 10,238 hours. The decrease in burden is due to the cycling out of selected components, and fewer burden hours for special studies/pretests.

16. Plans for Tabulation and Publication and Project Time Schedule

The data collected in NHANES will be released in several formats: public release Internet data sets, NCHS Vital and Health Statistics and Data Briefs, the CDC Morbidity and Mortality Weekly Report, CDC's National Report on Human Exposure to Environmental Chemicals, Congressionally mandated annual reports such as Health U.S. and Healthy People 2010, and journal articles. Data will be presented and disseminated at professional meetings. The schedule is below in Table 16-1. The NCHS Data Users Conferences provide an excellent

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means of notifying data users about upcoming data releases, showcasing the latest data releases, and providing tutorials on how to use NHANES data. Data will also be analyzed upon request by Federal health and nutrition policy committees, such as the U.S. Dietary Guidelines Advisory Committee and the National Academy of Sciences.

Analyses and presentations will be made by NCHS staff and other CDC staff in collaboration with consultants and staff from other Federal agencies and collaborating organizations. Schools of public health, research organizations, and individual researchers can analyze the NHANES data independently by using the public use data files. The release of public use files for the 2009-2010 NHANES is scheduled to begin by November 2011.

Published reports and presentations will address numerous topics in the areas of health status, nutritional status, and survey methodology. The prevalence of selected conditions and diseases will be established and normative distributions will be produced for many physiological and biochemical characteristics by age, sex and other demographic characteristics. Other reports will focus on the interrelationships between health conditions and risk factors assessed in NHANES or specific hypotheses that have been previously reported in studies involving population groups and subgroups.

Although the annual NHANES samples are nationally representative, analysts will need to pool data from several years to produce reliable estimates for most variables and health parameters of interest. Examples of analyses are listed below. This is not intended to be a complete listing of all planned analyses.

a. Health Status: Cross sectional and trends reports on the prevalence of conditions and risk factors such as hypertension, diabetes, urologic disease, smoking, infectious disease, physical activity, sexual behavior, abuse of alcohol and drugs and many other conditions are planned. Descriptions of dietary intake, physical activity, functional impairments, and distributions of biochemical measures including trends data are also planned.

b. Nutritional Status: NHANES measures both dietary intake and physiological and anthropometric measures of nutritional status. There will be reports on topics such as iron deficiency anemia, obesity, dietary supplements use, dietary intake, and deficiencies of selected biochemical indicators such as folate, and antioxidants. Comparisons of nutritional status and health status will also be done.

c. Special Reports: Information from the study will also be released in Health, U.S. and in reports by special groups such as the National Cholesterol Education Panel, the National Nutrition Monitoring and Related Research Program, the National High Blood Pressure Education Program, etc.

d. Methodology Reports: There will be NCHS reports describing all aspects of the design, content, conduct, and quality control of NHANES. The expected variability of estimates emanating from the study is covered in Part 2 of Section B of this supporting statement. This information will be published with each report. The NHANES implementation schedule, which includes the dates for availability of data, is shown below.

NHANES provides Analytic Guidelines to be used by NCHS staff and others using the NHANES public use data files. The December, 2005 version of the NHANES Analytic Guidelines (last corrected September 2006) is included in Attachment 7.

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Table 16-1 PROPOSED TIME SCHEDULE: NHANES PLANNING, DATA RELEASE, AND REPORTING ACTIVITIES

		2009	2010	2011	2012
Type of Activity	Planning Activities	Solicit/pilot proposals for 2011-2012	Pilot test new 2011-2012 components		
	Tabular Reports*	2007/2008 data		2009/2010 data	
	Micro-data Files (internet)			2009/2010 first release in November	
	Dietary Data**				2009/2010 data
	Research Data Center Access***				2009/2010 data

\* Produce limited “early release” data tables on specific topics of public health significance (special request).

\*\* Additional separate release of NHANES dietary recall data in accordance with DHHS/USDA survey integration plans.

\*\*\*NHANES variables not released on micro-data files due to disclosure risks. See information on NCHS Research Data Center and the NCHS Policy on Release of Micro Data.

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.

None