Supporting Statement for Request for Clearance

National Health And Nutrition Examination Survey

2007-2008

OMB No. 0920-0237

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Executive Summary

The National Center for Health Statistics (NCHS), Division of Health and Nutrition Examination Surveys (DHANES), part of the Centers for Disease Control and Prevention (CDC) has conducted a series of health and nutrition surveys since the early 1960s (OMB # 0920-0237). 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 National Health and Nutrition Examination Surveys (NHANES) were conducted on a periodic basis from 1971 to 1994. NHANES became a continuous, annual survey program in 1999. Each year, a nationally representative sample of the civilian, non-institutionalized U.S. population, all ages, is interviewed and examined.

Beginning in 2007 some changes have been made to the domains being oversampled. The primary change will be the oversampling of the entire Hispanic population instead of just the Mexican Americain (MA) population which has been oversampled since 1988. Sufficient numbers of MAs will be retained in the sample design so that trends in the health of MAs can continue to be monitored. Persons 60 and older, black Americans and the low income population will continue to be oversampled. The oversample of pregnant women and adolescents in the survey from 1999-2006 will be discontinued to allow for the oversampling of the Hispanic population. The restrictions imposed by the NHANES examination permit only about 5000 examinations per year. Therefore when a new domain to be oversampled is cycled in another oversampled domain must cycle out.

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 1999-2000, 2001-2002 and 2003-2004 cycles have been released at various times over the past few years and are posted on the NHANES website. The URL is http://www.cdc.gov/nchs/nhanes.htm. DHANES is seeking a three year approval to continue the NHANES and specifically to collect data for 2007-2008.

Survey response rates remain high. The interview and examination responses rate for 2005-2006 to date are 81% and 78% respectively. Innovative recruitment methods have contributed to the high response rates.

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 10-day letter mechanism.

A major advantage of continuous NHANES data collection is the ability to address emerging public health issues and provide objective data on more health conditions and issues. For 2007, the new examination, laboratory and questionnaire topics to be studied include:

- Introduction of the Flexible Consumer Behavior Survey (FCBS). This survey will gather information about nutrition knowledge, attitudes, and beliefs. This contributes to the major NHANES objectives of studying the relationship between diet, nutrition and health, as well as monitoring trends in risk behaviors and the prevalence of risk factors in population subgroups.

- The NHANES program will resume spirometry testing in 2007. The spirometry will be performed the same way as in the previous NHANES surveys with the following new enhancements: a) children ages 6 and 7 will undergo testing (the eligible age range will be 6-79 years); b) children and adults with airway obstruction detected by baseline spirometry will undergo repeat testing after inhalation of a short-acting β2-adrenergic bronchodilator; c) a measure of inflammation in the lungs will be introduced—the Exhaled Nitric Oxide (ENO) test.

- Presently, NHANES collects information on all prescription medicines used by participants in the month prior to interview. For 2007, additional questions will be added to assess asthma medication use among adults 20 years and older.

- NHANES will collect a 24 hour recall of dietary supplement data. This will be done using the same methodology and time frame as the 24 hour dietary recall in the MEC. Using the same methodology will allow total nutrient intake estimates.

- In 2007 measurement of omega-3 fatty acids for participants 3 and older will be added to the laboratory component. In recent years, mounting scientific evidence has led to recommendations for increased consumption of omega-3 fatty There are at least 10 ongoing NIH-funded studies testing the effects of omega-3 fatty acids for conditions such as bipolar disorder, cancer, anorexia/cachexia, retinitis pigmentosa, arrhythymias and stress. The reference data from NHANES will be useful for evaluation of the concentrations achieved in these intervention studies.

Several components are being cycled out in 2007, including cardiovascular fitness, body composition (DXA), physical activity monitoring and the food propensity interview. We have collected at least 4 years of data for each of those components. In the case of the Allergy component, our collaborator's research focus has changed.

The continuous survey design makes it possible to report on major public health topics in a timely and efficient manner. Contributions reported by NHANES users since the last OMB submission 2 years ago include:

- The third National Report on Human Exposure to Environmental Chemicals, July 2005 - This Third Report presents exposure information for the U.S. population for 148 chemicals included in the Report. The new chemicals for the Third Report are—pyrethroid insecticides, additional polycyclic aromatic hydrocarbons (including benzo-[a]-pyrene), aldrin, endrin, dieldrin, additional phthalate metabolites, additional pesticides and herbicides, additional dioxins, furans, and polychlorinated biphenyls (PCBs). The Report also includes the data from the Second Report; that is, data for 1999-2000. (Reference: CDC/NCEH, Third National Report on Human Exposure to Environmental Chemicals. July 2005. URL: http://www.cdc.gov/exposurereport/)

- Estimates comparing prevalence of dental caries, dental sealants, tooth retention, and edentulism in the United States from 1988-94 and 1999-2002. The status of dental caries in permanent teeth has improved since 1988-94; however, there was no change observed in the status of dental caries in primary teeth. Edentulism continues to decline and disparities remain in dental sealant use. (Reference: MMWR 54(No. SS-3): 1-44, August 26, 2005)

- Advance Data No. 361. Anthropometric Reference Data for Children and Adults: U.S.

Population, 1999-2002 - This report presents national anthropometric reference data based on health examination survey results from the National Health and Nutrition Examination Survey (NHANES), 1999–2002, for all ages of the U.S. population. These data add to the knowledge about trends in child growth and development and are used to monitor prevalent conditions in the U.S. population such as overweight and obesity (Reference: Advance Data No 361, July 7, 2005 URL: . http://www.cdc.gov/nchs/data/ad/ad361.pdf )

- Data from the 1999--2000 and 2001--2002 National Health and Nutrition Examination Surveys (NHANES) indicated that Mexican Americans, blacks, and younger adults were less likely to be screened for high blood cholesterol, and persons in those populations who had high cholesterol were less likely to be aware of their condition. (Reference: MMWR. 54(05):117-119, 2005 Feb 11.)

- The 1999-2000 NHANES data on dietary supplement use have been used to calculate prevalence of use by U.S. adults for any dietary supplement and for major supplement types overall and by a variety of socio-demographic characteristics. Length and frequency of supplement use and number of supplements taken have also been assessed. (American Journal of Epidemiology 2004 Aug 15;160 (4):339-49.)

- NHANES 1999-2002 data on visual impairment were analyzed by researchers at the National Eye Institute and showed that although “94 percent of Americans aged 12 and older have good vision, the remaining six percent, or 14 million, are visually impaired. Of these, more than 11 million have uncorrected visual impairment, such as nearsightedness. They need eyeglasses or contact lenses to improve their vision. Teenagers, people with diabetes, Hispanics, and people who are economically disadvantaged have higher rates of visual impairment and can most benefit from corrective lenses.” NEI plans to increase public awareness about the importance of routine eye examinations. (JAMA 2006 May 10: 295:2158-2163)

- The first national estimates of erectile dysfunction were provided by the 2001-2002 NHANES data. Researchers at the Urologic Diseases in America Project found that ” overall prevalence of ED was 18.4 percent, the authors report. ED occurred more often as men aged, affecting 6.5 percent of men aged 20 to 29 years and 77.5 of those aged 75 years and older. When considering other factors that might contribute to ED, including age and other medical conditions, Hispanic men had almost twice the risk of ED as white men. Obesity, hypertension, smoking and diabetes also were associated with risk of ED.” (Arch Intern Med. 2006;166:207-212)

The continuous survey design also makes early availability of the data possible. The first release of NHANES 2003-2004 data occurred in November, 2005. In planning for 2007-2008 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.

A. Justification

1. Circumstances Making the Collection of Information Necessary

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) The National Nutrition Monitoring and Related Research Act of 1990 (P.L. 101-445), (October 22, 1990) specifies that NHANES be maintained as a component of the comprehensive nutrition monitoring plan with continuous coverage of dietary and nutritional status for the population and high-risk subgroups. NOTE: The law was not reauthorized within the ten year time period of the law, but new legislation to re-authorize the legislation is expected to be introduced soon in Congress.
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. Attachment 2 includes a history of the NHANES and a summary of data uses from previous surveys. The current examination components and target age groups are listed in Attachment 3.

Survey response rates remain high. The interview and examination response rates for 2005-2006 to date are 81% and 78%, respectively. Innovative recruitment methods have contributed to the high response rates. The survey team developed targeted survey information brochures for special age and race/ethnic groups, new media materials to inform survey communities about the survey, and more local community group contacts as part of the advance arrangements process. Remuneration has also contributed to the high response rates for the examination and for components occurring after the examination. Special interpreters for languages other than English and Spanish are used as needed for the household interviews. The NHANES website --http://www.cdc.gov/nchs/nhanes.htm --includes an interesting site for survey participants; the site provides information about the study and features a virtual tour video of the NHANES mobile examination center (MEC). The advance letter has been translated into several languages other than English and Spanish to accommodate the diverse

population the interviewers meet at the doorstep. Recently we began sending a pre-advance letter postcard one week before the mailing of the advance letter (Attachment 7).

2. Purpose and Use of the Information Collection

The data from NHANES are used by government agencies, state and community health organizations, private researchers, consumer organizations, industry, and health providers. Uses of data from previous NHANES are listed in Attachment 2. Links to Medicare and National Death Index records are being used to conduct studies of mortality and health care utilization in the U.S. population. In 2002, the DHHS formally integrated dietary data collection activities with the U.S. Department of Agriculture (USDA).

The purposes and uses of each survey component are detailed below. The major components of NHANES are the health examination component, the laboratory component, and the interview component.

NHANES Examination Component

The following are new examination topics for 2007: 24 hour dietary supplement intake (c.) and spirometry and Exhaled Nitric Oxide (ENO) (f).

The following examination components have changes in 2007: body measures (d.), bone density (d.), and audiometry (g.)

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 lipid 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 the NHANES III. 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 (NHANES II, III, and 1999-2008) and impaired glucose tolerance (NHANES II and III, NHANES 2005-2008). 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, treatment and control of diabetes. The information along with the laboratory tests will be used to assess progress in the achievement of the goals of the National Diabetes Education Program. The ophthalmologic examination component (40 and older) will assess diabetic retinopathy in the diabetic and pre-diabetic population.

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. Beginning in 2007 24 hour intake of dietary supplements will be asked after the DR. The 24-hour DR data plus the corresponding dietary supplement intake will be used to estimate total intake of foods and nutrients for the population.

Additional questions related to diet are asked in the household questionnaire (Diet and Behavior Questionnaire (DBQ) and in the new FCBS telephone interview.

d. Obesity, Osteoporosis, Growth and Development

Body Measures

Obesity is a major epidemic in children and adults, with nearly two-thirds of U.S. adults now overweight and 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. The body measurement component will be shortened in 2007. The maximum calf and mid-thigh circumference measurements will be discontinued. This data has been collected for eight years. Discontinuing data that has been collected for several years is part of the mechanism that allows new content to be cycled into the survey.

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.

Bone Density

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) national 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 estimated by utilizing the bone mineral content and BMD obtained from dual-energy x-ray absorptiometry (DXA). Scans of the proximal femur and anterioposterior (AP) spine are administered to survey participants ages 8 years and older. In 2007, the whole body DXA scan done for body composition will be cycled out after being on the survey for 8 years. Discontinuing data that has been collected for several years is part of the mechanism that allows new content to be cycled into the survey.

e. Oral Health

The target age group for the Oral Health component is participants aged 5 years and older. The protocol, known as Basic Screening Examination (BSE), is unchanged from the NHANES 2005-2006 data collection cycle. Unlike NHANES oral health protocols employed before 2005, the BSE does not assess each tooth surface and the assessments are not made by a dentist. NHANES will use a simplified screening process to collect information on untreated caries, dental restorations, and dental sealants. In addition to performing the BSE the examiner will inquire about the use of dentures, perform a tooth count, and ascertain the number of dental contacts.

f. Respiratory Function

Spirometry Measurement

Spirometry is the measurement of exhaled lung volume and expiratory airflow rates. It is a standard lung function test in medical practice. The NHANES III spirometry survey (1988-1994) provided the principal source of U.S. national reference data for lung function testing. 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 has not been done in NHANES since 1994. The NHANES program intends to resume spirometry testing in 2007. The spirometry will be performed the same way as in the previous NHANES surveys with the following new enhancements: a) younger children ages 6 and 7 will undergo testing (the eligible age range will be 6-79 years); and b) children and adults with airway obstruction detected by baseline pulmonary function testing will undergo repeat spirometry after inhalation of a short-acting $\beta_2$-adrenergic bronchodilator.

If a participant has a FEV1/FVC% less than the lower limit of normal, then they may be considered for epidemiological purposes to have airways obstruction. Airways obstruction falls

into two general categories, 1) asthma and 2) chronic obstructive pulmonary disease (COPD). Asthma is defined as a condition where the airways obstruction is potentially reversible; whereas most commonly COPD represents fixed obstruction due to anatomic changes in the airways or scarring. In both routine clinical settings and in respiratory epidemiologic studies, bronchodilator reversibility testing is used to distinguish between asthma and COPD. For example if a participant with airways obstruction on baseline pulmonary function testing has reversibility of the deficit with administration of a short acting $\beta_2$-adrenergic bronchodilator, they may be considered to have asthma. If the deficit is not reversible, then they can be considered to have COPD. Although bronchodilator testing has been performed in many previous studies of respiratory health, it was not done in previous NHANES survey cycles. As a result there are currently not accurate national level estimates for the prevalence of asthma and COPD in the U.S. More accurate population based studies are needed to provide data for public health planning.

The Spirometric testing protocol for baseline spirometry will meet current American Thoracic Society (ATS) Guidelines for Spirometric Testing. Spirometry technicians will have demonstrated proficiency in spirometric testing, calibration, equipment maintenance, and quality control. They will also have completed the standard NIOSH Certified training course in Spirometric procedures, which meets ATS guidelines for Technician Training.

NHANES 2007-8 will do baseline spirometry on all participants ages 6-79 years. Based on NHANES III data, we estimate that approximately 10% of participants we test will have evidence of airways obstruction on their baseline spirometry tests. These participants will be asked to see the MEC physician for an evaluation, and if they are eligible and give their consent, a bronchodilator will be administered. Bronchodilator reversibility spirometry testing is a standard clinical procedure and has been employed in many population-based surveys of asthma and chronic obstructive pulmonary disease (COPD) both in adults and children. Bronchodilator reversibility testing is used to distinguish between asthma and COPD and other causes of fixed obstructive lung disease, and is used to determine asthma severity and the degree of treatment control.

After the bronchodilator administration a repeat spirometry will be performed. The physician's medical evaluation and consent for bronchodilator administration will be conducted in the Mobile Exam Center Physician's exam room. The physician will review the participant's health history and all current medications and a decision will be made as to whether the participant should be excluded from bronchodilator administration. If the participant is not excluded, the physician will then provide an overview of the component and the proposed use of albuterol, present the consent form and review it with the participant. The physicians will receive training in the potential adverse effects of albuterol, and will be instructed to review these with the participant prior to obtaining consent. The list of adverse reactions to be reviewed will include those related to the pharmacological and adverse effects of albuterol (rapid pulse, hypertension, transient tremor, etc.) and also potential allergic reactions. The potential side effects and "allergic reactions" will be discussed in language appropriate to the participant's level of understanding, and will include lists of symptoms (skin rash or hives; itchy, watery eyes, congestion, swelling of the face, difficulty breathing, and/or stomach cramping with nausea, or vomiting). Participants 18 years of age or older will provide documented consent. Parents or guardians of minor participants must be present to provide parental permission. Children 7-17 years of age must provide documented assent.

Exhaled Nitric Oxide (ENO) Measurement

Evaluation of airway inflammation, a precursor of asthma symptoms, is important in 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 often increase during the so-called late-phase reactions following exposures to an allergen, a phase which is characterized by the migration of inflammatory cells to the airways mucosa. There appears to be an association between NO in exhaled air and the number of eosinophils in sputum.

Data suggest there are large differences in ENO between asthmatics and healthy controls; ENO levels are 3 to 10 fold greater in asthmatics. These differences make the method sufficiently sensitive to detect cases of either mild asthma or incipient asthma, which are usually symptom-free. In addition, measurement of airway inflammation may reveal diseased airways not detectable by symptoms, clinical examination, questionnaire, baseline spirometry, or bronchodilator studies. In clinical studies, airway inflammation has been measured in secretions and biopsies obtained during bronchoscopy, but these methods are too invasive and not appropriate for use in epidemiological evaluations. NHANES is therefore conducting ENO testing to fulfill this need in data collection.

g. Sensory Performance

Audiometry (Hearing)

In 2007-2008 NHANES will cycle out the hearing test for participants 70 and older but continue for those 12-19. The expected low prevalence in teenagers requires more years of data collection to obtain reliable estimates.

The specific aims of this component are: 1) to update surveillance prevalence estimates of hearing loss in U.S. children and adolescents; 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. 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.

h. Vision Testing and Ophthalmology Examination

Diabetic retinopathy, age-related macular degeneration, other retinal diseases, and glaucoma are the leading causes of vision loss in the United States. Continuation of the fundus photograph and visual field testing in participants 40 and older to provide up-to-date nationally representative data on major eye problems and also help toward assessing progress for the Healthy People 2010 vision objectives. Participants 12 and older will continue to have visual acuity tested.

NHANES Laboratory Assessments

The following summarizes new laboratory tests/classes of analytes for 2007. Within environmental chemical exposure 2 new classes of chemicals have been added: parabens and polychlorinated naphthalenes. Within some categories of chemicals specific analytes have

changed (a.) These are noted on the table in Appendix 12B. Other new tests for 2007 are omega-3 fatty acids (c.), hepatitis C genotyping (b.), and complexed PSA (e.) Collection of specimens for genetic testing will resume in 2007 (d.).

This section describes environmental exposure, infectious disease and immunization status, nutritional biochemistry and hematology, a description of biologic specimen banking project activities and other laboratory tests.

a. Environmental Chemical Exposures

The NHANES environmental health component was expanded in 1999 in collaboration with laboratories of the National Center for Environmental Health (NCEH). NHANES 1999-2006 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 proposals for chemicals for inclusion in future releases of the National Report on Human Exposure to Environmental Chemicals by placing notices in the Federal Register (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. Although, the laboratory methods are not finalized, it is projected that NHANES 2007 and beyond will include the list of chemicals in Attachment 12b. Within classes of chemicals, analytes new in 2007 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.

These analytes fall under the following classes of chemicals:

- Cotinine
- 4-(Methylnitrosamino)-1-(3-pyridyl)-1-Butanol
- Heavy metals
- 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
- Acrylamide

- Perchlorate
- Polychlorinated naphthalenes
- Parabens

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
- 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 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 2007-2008 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 prior 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 will be used to establish population-based reference ranges and to evaluate the need for regulations to reduce levels of exposure.

Lead: Lead is a known environmental toxin that affects the nervous, hematopoietic, endocrine, renal and reproductive systems. In young children, lead exposure is a particular hazard because children more readily absorb lead than do adults, and children's developing nervous systems also make them more susceptible to the effects of lead. The primary sources of exposure for children are lead laden paint chips and dust as a result of deteriorating lead-based paint. The risk for lead exposure is disproportionately higher for children who are poor, non-Hispanic black, living in large metropolitan areas, or living in older housing. Among adults, the most common high exposure sources are occupational.

Blood lead levels measured in previous NHANES programs have been the cornerstone of lead exposure surveillance in the U.S. The data have been used to document the burden of and dramatic decline of elevated blood lead levels; to promote the reduction of lead use; and to help to redefine national lead poisoning prevention guidelines, standards and abatement activities.

Cadmium: Cadmium is used in batteries, pigments, metal coatings, and plastics. Cadmium enters the environment from the weathering and mining of rocks and minerals that contain cadmium. Contaminated water sources, foods, and combustion sources may also result in human exposure. Cadmium exposure occurs from inhalation of cigarette smoke. Exposure to cadmium may occur in industries, such as mining or electroplating, which use or produce the chemical. Once absorbed into the body, cadmium may remain for decades. Low level chronic exposures over many years may result in accumulation of cadmium in the kidneys. Chronic ingestion also has produced painful osteomalacia, a bone disorder similar to rickets in children. Large, acute airborne exposures to dusts and fumes, as occurs for example from welding on cadmium-alloyed metals, may result in severe swelling of the lungs (edema) and subsequent scarring (fibrosis). Other cadmium toxicity, as seen in animal studies, includes reproductive and teratogenic effects. The International Agency for Research on Cancer has determined that cadmium is a known human carcinogen.

Mercury: NHANES 2007-2008 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. Mercury is widespread in the environment and originates from natural and anthropogenic sources. The general population may be exposed to three forms of mercury: elemental, inorganic, or organic (primarily methylmercury). Elemental and inorganic mercury exposure can result from mercury spills, dental amalgams, and occupational exposures. Methylmercury is formed, through microbial action from inorganic mercury that deposits in

aquatic environments and bioaccumulates in the food chain. Exposure occurs primarily through consumption of seafood and/or freshwater fish, particularly larger predatory fish. Methylmercury is a well-established human neurotoxin and the developing fetus is most sensitive to the adverse effects. The concentration of total mercury in blood is a reasonable biomeasure of methylmercury exposure. The concentration of total mercury in urine is a biomeasure of exposure to inorganic mercury. NHANES 1999-2002 provided the first estimates of exposure for US children and women of childbearing years based on measurements of total mercury in blood and total mercury in urine (women only Mercury assessments will be conducted in persons 1 year of age and older; urinary mercury will be measured in persons 6 years of age and older.

Arsenic: Arsenic is widely distributed in the earth's crust and is found most often in ground water rather than surface water. People encounter arsenic in many chemical forms that vary greatly in toxicity. The most toxic of the naturally-occurring arsenic compounds are inorganic forms of arsenic and their methylated metabolites. Less toxic are the organic arsenic compounds. Exposure to inorganic arsenic can result in a variety of adverse health effects, such as skin disorders, nerve impairment, cancer of the liver, bladder, kidneys, prostate, and lungs, and even death from large doses. People may be exposed to inorganic arsenic through activities such as drinking water contaminated from geological sources or because of occupational exposure, especially breathing air contaminated with sawdust or smoke from wood treated with chromated copper arsenic preservatives. Organic arsenic compounds are generally less toxic and may be encountered by ingesting various types of fish, shellfish, poultry or seaweed. Adverse health effects resulting from arsenic exposure include hematopoietic and immune system changes, cardiovascular and neurological disorders, as well as skin and internal cancers. In January 2001 the Environmental Protection Agency (EPA), in compliance with the 1996 Safe Drinking Water Act (SDWA) proposed a lower Maximum Contaminant Level (MCL) for arsenic in drinking water. The previous MCL was 50 ppb, a standard that was set by the U.S. Public Health Service in 1947. The new level proposed by the EPA is 10 parts per billion (ppb), the same limit is used by the World Health Organization (WHO).

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). 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. While background level ranges of PAHs in air and water are known, the equivalent metabolite background levels in humans are not known.

Non-persistent pesticides (organophosphate insecticides, pyrethroid pesticides, other pesticides and fungicides, and herbicides): In the 2007-8 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. Additional pesticide metabolites in urine are added in 2007-2008 because of development of laboratory methods. In 1999, about five billion pounds of pesticide active ingredients were used in the US, most of it for agricultural applications. The most recent registration data provided by the US EPA showed over 800 pesticidal active ingredients available in about 21,000 different formulations. Widespread use of the contemporary pesticides for agriculture and residential applications makes it virtually impossible for the average person to completely avoid exposure. Pesticide residues and their metabolites in human tissues and fluids can be indicative of pesticide exposure and the total body burden of these pesticides. Exposure to several pesticides was assessed by measuring urinary pesticide metabolites during NHANES 1999-2002. However, determination of the specific pesticide linked to the exposure can be inaccurate because some metabolites are common to multiple pesticides. Beginning in NHANES 2003-2004, specific pesticides in blood were also measured.

Little information is available concerning residential or household exposures to pesticides among the general population. Sufficient data do exist, however, from surveys or other focused research efforts to suggest that household exposure to certain common pesticides can be extensive and might be of significant public health concern. Pesticides of particular concern are: chlorpyrifos, 2,4-D, diazinon, permethrin, ortho-phenyl phenol, methyl parathion, and organophosphate pesticides.

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, and there is increased concern regarding the toxicity of these perfluorinated compounds, including perfluorooctanoic acid (PFOA) and perfluorooctanesulfonate (PFOS).

PFOS has been used in a wide variety of industrial and consumer products including protective coatings for carpets and apparel, paper coatings, insecticide formulations, and surfactants. In May 2000, the 3M Company, the sole manufacturer of PFOS in the United States and the principal manufacturer worldwide, announced that it was discontinuing the production of fluorochemicals, including PFOS. PFOA is used primarily to produce its salts which are used in the production of fluoroelastomers and fluoropolymers, such as polytetrafluoroethylene (PTFE) and polyvinylidine fluoride (PVDF). PFOA is still being produced (e.g., by DuPont). 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. 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. Such information suggests that more information is needed to evaluate the degree of human exposure in the US population.

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 2007-2008 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 on May 7, 2004 when FDA released extensive data showing levels of this potential human carcinogen in food products.

Volatile organic compounds (home tap water): In addition to assessing levels of VOCs in blood, VOC levels will be measured in home tap water specimens provided by NHANES participants. The list of water VOC analytes was expanded in NHANES 2005 to include new water disinfection byproducts (5 halonitromethanes and 2 iodotrihalomethanes) and new fuel oxygenate ethers that may be used to replace Methyl Tertiary Butyl Ether (MTBE). The new water disinfection byproducts are more toxic than the currently regulated trihalomethanes. Widespread exposure to potentially toxic new fuel oxygenates may occur as MTBE usage is decreased.

Trans-fatty acids: Trans-fatty acids are produced when liquid oils are chemically modified to give solid fat - a process called hydrogenation. From the widespread use of trans-fatty acids in

processed foods, the majority of the US population is exposed. Because of their unique structure, trans-fatty acids have biological activities that are different from those of naturally occurring unsaturated fatty acids. Controlled intervention (feeding) studies in different population groups in the United States and other countries consistently indicate that consumption of diets containing trans fatty acids results in elevations of serum LDL-C (the major dietary risk factor for coronary heart disease, CHD) compared with consumption of diets containing naturally occurring unsaturated fatty acids. The relationship between the intake of trans fatty acids and coronary heart disease is now established. In response to health concerns, the FDA has issued requirements for food manufacturers to identify trans-fatty acids in their products. The trans fatty acid content in food has been limited in many other countries.

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. Though acrylamide is known to cause adverse health effects and biomarkers exist to assess exposure to this chemical, no data on the actual acrylamide exposure in the population exist. Filling this knowledge gap 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. Despite the potential health effects of perchlorate exposure, widespread use of perchlorate salts coupled with little regulation concerning its disposal 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. Industries using perchlorate in the past have legally dumped large amounts into unlined lagoons resulting in large plumes of contamination in many areas of the United States.

Polychlorinated naphthalenes (PCNs): Methods became available to measure serum levels of this class of chemicals so they have been added to the protocol in 2007-8. 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 to be 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: Methods became available to measure serum levels of this class of chemicals so they have been added to the protocol in 2007-8. Parabens (alkyl esters of p-hydroxybenzoic acid) are a group of phenols widely used as antimicrobial preservatives in cosmetic products, pharmacerticals, and food processing. Some parabens possess weak estrogenicity, although toxic effects of parabens in humans are mostly unknown. Recently, butyl paraben was nominated by the National Institute of Environmental Health Sciences for toxicological characterization, including reproductive toxicity studies. 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. Four new phenols, namely methyl paraben, ethyl paraben, propyl paraben and butyl paraben will be measured starting with NHANES 2007.

b. 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. Active infection with Chlamydia trachomatis and Neisseria gonorrhoeae can be evaluated in a urine specimen using Ligase Chain Reaction assays. Current human papilloma virus (HPV) infection will be evaluated via the collection of a vaginal swab to examine for DNA from specific high and low risk sub-types of HPV.

Urine from examinees ages 14-39 will be tested for Chlamydia trachomatis and Neisseria gonorrhoeae using ligase chain reaction assays. NHANES offers an opportunity to assess the prevalence of chlamydial and gonococcal infection in the general population and to monitor trends in prevalence as prevention programs are established and expanded.

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), hepatitis B surface antigen (6 years and older); hepatitis C enzyme immunoassay, with positives confirmed and HCV RNA genotyping of positive specimens (6 years and older). In 2007, the Hepatitis C genotyping is the only change in the protocol. 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.

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.

Sera from examinees ages 18-49 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 99-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.

Genital human papilloma virus (HPV) infection is likely the most common sexually transmitted infection in the U.S., and cervical infection with certain types of HPV, especially HPV-16, is the single strongest risk factor for cervical cancer. Sera from individuals aged 14-59 years will be tested for antibody to HPV-16. Women aged 14-59 years will be tested for HPV DNA (high-risk

and low-risk types) to estimate current infection with these types of HPV. 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. Self-administered vaginal swabs will be used to detect current HPV infection. Detection and typing of HPV DNA in vaginal swabs will allow estimation of type-specific HPV prevalence by age, race/ethnicity and sexual behavior. HPV vaccine was approved in June 2006 increasing the importance of continuing to monitor this infection.

c. Nutritional Biochemistries and Hematologies

HANES 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 $B_6$, and vitamin D will continue in 2007. Vitamin C, vitamin A, vitamin E, vitamin $B_{12}$, serum carotinoids, methylmalonic acid, erythrocyte protoporphyrin and homocysteine, and will be cycled out in 2007. This data has been collected for multiple years. Discontinuing data that has been collected for several years is part of the mechanism that allows new content to be cycled into the survey.

In 2007 measurement of omega-3 fatty acids for participants 3 and older will be added to the laboratory component. In recent years, mounting scientific evidence has led to recommendations for increased consumption of omega-3 fatty There are at least 10 ongoing NIH-funded studies testing the effects of omega-3 fatty acids for conditions such as bipolar disorder, cancer, anorexia/cachexia, retinitis pigmentosa, arrhythymias and stress. The reference data from NHANES will be useful for evaluation of the concentrations achieved in these intervention studies.

d. Biologic Specimen Banking:

Serum, plasma and urine will continue to be stored for future research. Collection of a genetic specimen will resume in 2007 after a four year hiatus

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.

e. Other laboratory

Prostate Specific Antigen (PSA): Total and free serum PSA among men 40-70 years of age will continue to be measured. Additionally, in 2007 we will add complexed PSA (cPSA) to the PSA profile to establish national age and race specific population reference values.

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 persons with chronic kidney disease.

Liver function: NHANES' biochemistry profile provides some indication of liver function to be analyzed in concert with the Hepatitis profile.

NHANES Interview: Special Topics

The following new special topic questionnaires/sections have been added for 2007: the Flexible Consumer Behavior Survey telephone interview and the Consumer Behavior section of the Family Household questionnaire (a.).

The following special topic questionnaire sections have changes in 2007: nutrition program participation questions on WIC (b.), reasons for dietary supplement use (e.), prescription drug use (f.), current health status (j.), and physical activity (k.).

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.

a. Flexible Consumer Behavior Survey (FCBS)

The FCBS will fill a major gap in information related to the eating habits of Americans that was left by the discontinuation of USDA's Diet Health Knowledge Survey (DHKS) after 1996. The new survey will reinstate and continue the core function of the DHKS by gathering information about the nutrition knowledge, attitudes, and beliefs. The NHANES core data on dietary intakes and nutritional biomarkers will be linked to participants' knowledge, attitudes and perceptions related to food. Assessing such linkages in various population subgroups and how the linkages change over time will provide critical information not only to public health experts and policymakers, but to the food industry and the growing food-away-from-home sector as well. Information gathered by the FCBS will contribute to the major NHANES objectives of studying the relationship between diet, nutrition and health, as well as monitoring trends in risk behaviors and the prevalence of risk factors in population subgroups. The Economic Research Service of the US Department of Agriculture received input for these questions from other parts of USDA, from DHHS (FDA, NCI) and the EPA.

The questions that constitute the FCBS were added to the household individual and family questionnaire and to a new telephone interview. The questions can be found in the Income, Food Security, and Consumer Behavior section of the Family questionnaire and the Diet and Health Behavior section of the Sample Person Questionnaire. These questions were highlighted in the 'Ten-Day' letter submission for the pilot test of the telephone interview as requested by OMB.

The questions cover seven broad topic areas. The majority of the questions are in the telephone interview. The seven topic areas are: income and assets, food expenditure and time use, food assistance programs (Food Stamp and WIC), self-assessed diet quality and habits, use of prepared foods/ food away from home, knowledge and attitudes (price, taste, MyPyramid), and nutrition label use.

b. Food Security and Nutrition Program Participation

The 2007-2008 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. It is anticipated that during the 2007-2008 NHANES, testing of potential new food security questions will occur in response to the National Research Council's 2006 report, *Food Insecurity and Hunger in the United States: An Assessment of the Measure*.

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. Additional questions on past participation in the WIC program have been added for children 6-11 as part of the FCBS.

A feasibility/pilot test linking NHANES records to Food Stamp and WIC Program administrative records is planned for late CY 2006 based on data from one NHANES location from NHANES 1999-2005. If successful this may become part of the protocol for the NHANES 2007-2008 cycle of NHANES. A 'ten-day' letter to OMB will be generated when a detailed protocol is developed.

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. Sleep Disorders

Beginning in 2005, older adolescents and adults (16+ years) were asked a series of questions related to sleep. The questions are derived from the Sleep Habits Questionnaire (SHQ) and the Functional Outcomes of Sleep Questionnaire (FOSQ). Most of the questions have been widely used and validated in previous studies. The questions from the FOSQ will be used to assess the impact of sleepiness on multiple activities of everyday living. The data combined with associated risk factors, life style information and other information collected during the examination will provide the opportunity to examine the inter-relationship between sleep and significant public health concerns including cardiovascular disease, obesity, and diabetes.

d. Pelvic Floor Disorders and Bowel Health

A pelvic floor disorder and 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. These bowel disorders are among the risk factors for pelvic floor disorders. Pelvic floor disorders are a group of clinical conditions that include urinary incontinence, nocturia, pelvic organ prolapse, fecal incontinence, and other sensory and emptying abnormalities of the lower urinary and gastrointestinal tract. The bowel health questions are also being asked of men 20 years and older to obtain the first national prevalence estimates of fecal incontinence and defecatory dysfunction in men 20 years and older.

e. Dietary Supplement (DS) Use

All sample persons are eligible for this section of 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.

NHANES 1999-2000 shows that that over half of US adults take some type of DS, these data are important for calculating total nutrient intake and estimating the proportion of people taking supplements of nutrients or non-nutrients of particular interest in relation to health. Therefore the 2007-2008 NHANES will increase the information it collects on DS use. As discussed

previously, after the two dietary recalls collected in the MEC and on the telephone we will collect a 24 hour dietary supplement intake recall. 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. Additionally, we will ask why respondents take DSs and antacids. Answer categories are based on a methodological study we conducted the first 6 months of 2006 where we asked the question in an open-ended fashion. For each supplement reported in the household interview, the participant will be asked the reason that the person is taking the supplement.

f. Prescription Drug Use

Survey participants are asked to report all prescription medications they used during the past month. The drug product labels are shown to the interviewer in the respondent's home whenever possible; interviewers access an electronic drug database listing to record the name of the product taken. The database facilitates data entry and improves the accuracy of drug reporting in the Survey. 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.

For 2007, additional questions will be added to assess asthma medication use among adults 20 years and older. Specifically we will be asking about chronic monthly use of asthma medications, that is, the use of the medicine every day or nearly every day during the past 3 months. We will also be collecting the specific name of the product, its strength and dosage, and daily frequency of use. These questions will be used to examine asthma medication use among US adults in more detail.

g. Mental Health (Depression)

Beginning in 2005, a depression screener questionnaire is being asked of 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$^{th}$ 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

h. Weight History and Weight Behavior

Children and adolescents are especially prone to fad 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 was 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 current 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.

i. Urologic Health

Self-reported information on bowel health, urinary incontinence and nocturia, prostate cancer, and benign prostatic hypertrophy will be collected. This 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 that will be used in concert with the prostate specific antigen (PSA) data collected for the laboratory component.

j. Current Health Status

Two additional questions are being added to the Current Health Status (HSQ) module of the Mobile Examination Center (MEC) interview. One question will collected information on pain. The second question will collect information on anxiety.

k. Physical Activity, and Function Assessments

In 2007 the Physical Activity Monitor and the Cardiovascular Fitness Examination have cycled off the survey. Considering this and the respondent burden of the previous question we have replaced them with the Global Physical Activity Questionnaire (GPAQ) which was developed at a World Health Organization (WHO) expert meeting in Hobart, Australia in 2002. The GPAQ builds on previous work undertaken with other instruments including the International Physical Activity Questionnaire (IPAQ). Data from the GPAQ can be used to produce prevalence estimates of Healthy People 2010 goals for physical activity and provides the necessary detail to be used as a covariate to describe fitness level in NHANES analysis.

The survey continues to assess the prevalence of physical and functional limitations. Extensive interview information on self-reported physical abilities and limitations is collected to assess the capacity of the individual to do various activities without the use of aids, and the level of difficulty in performing the task. Information is also collected on activities of daily living (ADLs) needed to maintain personal care. In addition, the questionnaire addresses play, educational, work, instrumental, and social activities of daily living (IADLs).

l. 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 2007.

**Supporting 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 2007 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 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. Two questions are being dropped in 2007 because they are redundant with other questions.

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.

More than 20 questions are being dropped in 2007 to streamline this part of the MEC interview and reduce respondent burden. Dropped questions are those that are not directly related to a specific examination or laboratory component. Most of these were part of the RHQ questionnaire since its inception (8 years). Eight new questions related to gestational diabetes and WIC receipt have been added.

Sexual Behavior: 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.

For 2007 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.

Drug Use: Questions on drug use are included for participants 14-59 years. The questions focus on lifetime use of street drugs or recreational drugs and the intravenous use of these drugs. Additional questions on age of initiation of drug injection, duration of injection drug use, and lifetime history of drug treatment are included in this section. 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 2007 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.

Other questionnaire changes for 2007

1. Blood Pressure (BPQ)—A question about prehypertension has been added.
2. Audiometry (AUQ) --Audiometry examination data will no longer be collected for SPs ages 70 therefore related questionnaire items will be discontinued. Four questions for this age group will still be administered to support tracking HP 2010 goals.
3. Demographics (DMQ)--Questions about foreign travel related to a previously discontinued component will be eliminated.
4. Immunization (IMQ) --Added questions about Human papilloma virus vaccine receipt for girls and women.
5. Occupation (OCQ)—Questions on occupational dust exposure added to accompany the spirometry examination and a single question is being added regarding industry/business for the longest job.
6. Condition list (MCQ). Added a gout question for trends from NHANES III and added a question to accompany the focus in Prescription section (RXQ) on asthma drug use.
7. Kidney (KIQ)--Two NHANES III questions on kidney stones for adults added back to monitor trends.
8. Respiratory (RDQ)--The Allergy questionnaire is being dropped for 2007-2008 because the corresponding objective data is cycling out. A single question will be moved to the RDQ section as a covariate ( a marker of personal atopic status) in the analysis of Spirometry examination data.
9. Weight history (WHQ)—An additional question on desired weight will be added.
10. Housing characteristics (HOQ) --Questions related to the discontinued allergy component will be dropped in 2007.

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

One objective of continuous NHANES is to provide a mechanism to respond to emerging and re-emerging public health topics. The content of the survey is modified biannually to accomplish this objective. Survey modifications may include removing or “cycling out” survey content that has been in the survey for multiple years, modifying existing survey content to include new target age groups, modified data collection methods, the use of updated technology, and the addition of new interview, laboratory, and examination components and topics. The NHANES Program utilizes a public proposal solicitation process to develop recommendations for survey content. The process and proposal guidelines are posted on the NHANES website

(http://www.cdc.gov/nchs/about/major/nhanes/research_proposal_guidelines.htm). NCHS disseminates 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. 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.

Continuous NHANES has enjoyed robust interview and examination response rates. Maintaining these response rates is a constant challenge. The survey requests clearance to conduct nonresponse evaluation studies to investigate the causes and potential remedies for nonresponse as they occur in specific subgroups of the population as needed.

The survey expects to continue conducting pilot studies for future cycles of continuous NHANES. During 2007-2008, pilot studies will be conducted to prepare for implementation during NHANES 2009-2010. Plans for future pilot studies have not been finalized. Possibilities are mentioned in section B.4. Pilot tests.

3. Use of lnformation Technology and Burden Reduction

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.

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 same type of detailed health and dietary interviews, laboratory tests, and health examinations 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 (see Attachment 4). The organizations contacted are listed in Attachment 5-1 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 important uses of previous NHANES data, listed in Attachment 2, support the need for the continuous collection of objective health data as is done in NHANES for program planning and health policy formation.

Respondents will participate in the data collection only one time. This may include follow-up studies. 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. Two telephone interviews occur after the examination. A second dietary recall is obtained on survey participants 2 and older. Adult sample persons who completed the second dietary recall will receive the Flexible Consumer Behavior Survey (FCBS) and be asked two questions regarding why they chose to participate in NHANES. 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

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 2007-2008 NHANES plans. The DHHS Office of the Assistant Secretary for Planning and Evaluation has reviewed the NHANES 2007-2008 plans (as outlined in the OMB package). 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.

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 5.

a. Federal Register Notice

In compliance with 5 CFR 1320.8(d), a notice soliciting comments on the collection for NHANES was published in the Federal Register on April 3, 2006 (Volume 71, Number 63, page 16580). No comments were received. Attachment 6 is a copy of the notice.

b. Other Outside Consultation

New content proposals were solicited for the 2007-2008 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 (Attachment 4). Approximately 20 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 the spirometry examination, the Flexible Consumer Behavior Survey (FCBS), and a 24 hour recall of dietary supplements.

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. 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.

In 2000 a large incentive experiment (n=5,445) was carried out in NHANES comparing $100 to $155 for remuneration for having the examination at the correct time. There was absolutely no difference in the response rates in the two incentive groups therefore the remuneration remains at $100 for participants 16 and older attending the correct examination session.

Current payment information

In the NHANES survey, an incentive of $70 is given to each examined sample person age 16 and older. They receive an additional $30 if they come to the correct session. Children 12-15 receive an incentive of $30. They receive an additional $20 if they come to the correct session. Children under 12 years of age receive just $30 for the basic exam since they are not asked to come in at a pre-selected time.

Participants who are examined at the MEC receive $30 additional incentive by mail after they participate in a dietary interview that is conducted by telephone a few days after the initial in-person dietary interview in the MEC. Participants who complete the consumer behavior questionnaire on the telephone receive an additional $15 incentive upon completion.

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 payment is remunerated. If sample persons 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.

The following is the NHANES remuneration schedule for 2007.

| **Payment condition** | **Payment** |
|---|---|
| SPs 16+ who agree to fast and be examined at pre-selected time | $100 |
| SPs 16+ who fail to fast and be examined at pre-selected time | $70 |
| SPs 12 – 15 who agree to fast and be examined at pre-selected time | $50 |
| SPs 12 – 15 who fail to fast and be examined at pre-selected time | $30 |
| SPs under age 12 | $30 |

**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 |

**Parental payment**

Non-SP parents of SPs under 16 years -- $20 one-time payment

**Post-primary exam payment**

| | |
|---|---|
| Dietary Phone Follow Up | $30 |
| Flexible Consumer Behavior Survey (FCBS) | $15 |

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."

Consequently, all information collected in NHANES will be kept confidential, with an exception for suspected child abuse, and no information that would identify an individual respondent will be released. Section 308(d) of the Public Health Service Act (42 U.S.C. 242m) provides NCHS with authority to collect information and stipulates that: "No information, if an establishment or person supplying the information or described in it is identified, obtained in the course of activities undertaken or supported under section 304, 305, 306 (NCHS legislation), 307, or 309 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 304 or 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 (PL 107-347) which states:

"Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by section 512, comes into possession of such information by reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this title, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than 5 years, or fined not more than $250,000, or both."

An Advance Letter 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 (see Attachment 8).
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 Statement" (Attachment 9). 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 identifying or identifiable information 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 (Attachment 10). 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 identifiers are removed from the public release files; this includes participant name, address, survey location number, sample person number, and so forth. A concerted effort is made to avoid any disclosures, such as detailed geographic information that may allow a researcher to go back and find individuals in the general population.

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").

11. Justifications for Sensitive Questions

Objective data of a sensitive nature are described in this section. All content of a sensitive nature in the examination is explicitly discussed in the NHANES informed consent document (Attachment 8).

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 in the Department, such as the National Death Index (NDI) to the survey information. Additionally, in 2007-2008 NHANES will use the SSN to link with Food Stamp Program and Women, Infants and Children Program administrative records from the USDA.

The following disclaimer currently accompanies the request for SSN: 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 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.

The following disclaimer will accompany the request for Medicare number: "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 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 11). 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 gonorrhea and selected strains of human papilloma virus (HPV). Information is obtained through questionnaire, 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 Household Survey on Drug Abuse, National Survey of Family Growth (NSFG) 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.

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 incontinence: 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 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. 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 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, and specifically for the 2007-2008 NHANES. These data collections will occur within the context of ongoing data collection activities (OMB 0920-0237). The burden for each survey component of one complete survey cycle is shown in the table below. As shown below, the estimated total burden for the 2007 survey is 59,864, including screening, follow up interviews, tests of procedures and special studies.

Annually, approximately 18,813 respondents are screened for the survey. Of these 13,333 are screened out of the sample and 5,480 are eligible for NHANES. Then, 300 complete the screener and the household interview, but decline to be examined. The remaining 5,180 participate in the examination. There are two components that occur after the examination. 4,300 participate in the second dietary recall interview done by telephone and 3,000 participate in the Flexible Consumer Behavior Survey (FCBS) telephone interview. Up to 4,000 additional persons might participate in follow-up surveys, tests of procedures and special studies. Thus the grand total of respondents is 22,813 and the total number of responses is 30,113.

NOTE: Assumptions made for Table 1 below are based on field experiences during NHANES 1999-2003. Maximum burden hours for ongoing process improvement and pilot testing are included.

TABLE 1 – ANNUALIZED BURDEN HOURS AND COSTS

| Burden category | Number of respondents per year | Number of responses per respondent | Average burden per response (hours) | Total respondent burden (hours) |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| 1. Screening interview only | 13,333 | 1 | 10/60 | 2222 |
| 2. Screener, family, and sample person interviews only | 300 | 1 | 1.10 | 330 |
| 3. Screener, family, and sample person interviews and MEC examination (including pilot studies) | 5,180 | 1 | 5.9 | 30562 |
| 4. Second dietary recall interview | 4,300 | 1 | 30/60 | 2150 |
| 5. Telephone Interview (FCBS) | 3,000 | 1 | 20/60 | 1000 |
| 6. Follow-up, special studies, and tests of procedures. | 4,000 | 1 | 5.9 | 23600 |
| Total | | | | 59,864 |

B. Cost to Respondents

The hourly wage rate of $16.62 per person is based on income from wages and salary from the BLS Employment Situation Summary Table A of average hourly earnings May, 2006. This wage rate for all persons was used since respondents do not fall into a single economic or occupational category. The total cost was $994,940 or $43.61 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 tests of the laboratory component (Attachment 12) 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 2007.

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 | $40,350,000 |

Table 2. Survey support from outside NCHS*

| Agency (component) | FY2007 | FY2008 |
|---|---|---|
| CDC, NCCDPHP, DOH (Oral Health) | 250,000 | 250,000 |
| CDC, NCCDPHP, DDT (Diabetes) | 400,000 | 400,000 |
| CDC, NCCDPHP, DDT (Vision) | 600,000 | 600,000 |
| CDC, NCCDPHP, DACH (Quality of Life) | 150,000 | 150,000 |
| CDC, NCCDPHP, OSH (Smoking & Health) | 250,000 | 250,000 |
| CDC, NCCDPHP, DCPC (PSA Testing) | 300,000 | 300,000 |
| CDC, NCCDPHP, DNPA (Nutrition) | 500,000 | 500,000 |
| CDC, NCHSTP, DSTDP (Sexual Behavior) | 500,000 | 500,000 |
| CDC, NCID, DVHP (Hepatitis) | 300,000 | 300,000 |
| CDC, NCBDDD, DBDDD (Folate) | 150,000 | 150,000 |
| CDC, NCEH, DLS (Labs and Environment) | 700,000 | 700,000 |
| USDA, ERS (Food Security) | 150,000 | 150,000 |
| USDA, ERS (Consumer Behavior Survey) | 800,000 | 700,000 |
| FDA, CFSAN (Nutrition Assessment) | 250,000 | 250,000 |
| EPA, OPPTS (Dietary Recall) | 300,000 | 300,000 |
| NIH, NCI, DCCPS ( Weight History) | 100,000 | 100,000 |
| NIH, NEI (Vision) | 350,000 | 350,000 |
| NIH, NHLBI (CHD and Sleep) | 2,300,000 | 2,100,000 |
| NIH, NIA – DXA | 400,000 | 400,000 |
| NIH, NIAMS – DXA | 300,000 | 300,000 |
| NIH, NIDCD – (Hearing) | 300,000 | 300,000 |
| NIH, NIDDK – (Diabetes) | 350,000 | 350,000 |
| NIH, NIDDK – (Kidney) | 500,000 | 500,000 |
| NIH, NIDDK – DXA | 100,000 | 100,000 |
| NIH, ODS (Dietary Supplements) | 1,500,000 | 1,500,000 |
| USDA-ARS-(24-hr dietary recall) | 2,300,000 | 2,300,000 |

| | | |
|---|---|---|
| TOTAL | 14,100,000 | 13,800,000 |

*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 62,974. We are now requesting approval for 59,864 hours, a decrease of 3,110 hours. The small decrease in burden is due to the cycling out of selected components. 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 6). 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 6 burden.

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 Advance Data reports, 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 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 2007-2008 NHANES is scheduled to begin by January 2010.

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. Decisions will need to be made as to when to release data for certain low-prevalence conditions if there are only two years of data available. Field operations, expensive equipment purchases and mobile trailer renovations require a long range commitment to data collection.

Examples of analyses are listed below. This is not intended to be a complete listing of all planned analyses. Examples of applications of data collected in past NHANES surveys are described in Attachment 2.

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. A report on quality control procedures used in the survey is also planned along with a nonresponse evaluation report. 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.

DHANES 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 is included in Attachment 13C.

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

| | | 2007 | 2008 | 2009 | 2010 |
|---|---|---|---|---|---|
| Type of Activity | Planning Activities | Solicit/pilot proposals for 2009-2010 | Pilot test new 2009-2010 components | | |
| | Tabular Reports* | 2005/2006 data | | 2007/2008 data | |
| | Micro-data Files (internet) | | | | 2007/2008 first release In January |
| | Dietary Data** | | | | 2007/2008 data |
| | Research Data Center Access*** | | | | 2007/2008 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

B. Collection of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

The sample design of NHANES is based on a continuous on-going annual survey of the non-institutionalized, civilian population of the U.S. Each single year and any combination of consecutive years comprise a nationally representative sample of the U.S. population. This design will allow limited national estimates from NHANES every two years.

Table 1, Attachment 13, B shows the sampling domains for NHANES. These domains represent the analytic subpopulations of interest, i.e., there is a need to make estimates of health characteristics within these subpopulations. For NHANES 2007-2010, there are 72

sampling domains defined by race/ethnicity, gender, age, and, for the white/other domains, low income status (i.e., households in which the household income is below 130% of the poverty level).

Table 2, Attachment 13, B shows the annual and cumulative estimates of the target sample sizes by analytic subdomain, based on the assumption that two Mobile Examination Center (MEC) teams will be in operation and approximately 5,000 persons will be examined in 15 primary sampling units (PSUs) per year. The expected sample size is based on past NHANES experience with response rates for each subdomain of interest. The goal for the overall examination response rate for NHANES 2007-2010 is to average 76 percent. In NHANES 1999, 2000, 2001, 2002, 2003, 2004, and 2005, the examination response rates were 72, 80, 81, 78, 75, 76, and 78 percent, respectively.

Table 3, Attachment 13, B presents the projected population size, number of sample persons and projected response rates for NHANES in 60 PSUs over a period of four years, by age, race-ethnicity, and gender.

2. Procedures for the Collection of Information

Data Collection Procedures

Westat, Inc will carry out the data collection under contract. Westat's responsibilities are to select Primary Sampling and other Units of the sample design, list the segments selected, make advance arrangements for each location, develop publicity/outreach methods and materials, set up and maintain field offices, set up and maintain the MECs, translate all questionnaires into Spanish, hire the field staff, create manuals and training programs for all field procedures (including training in NCHS confidentiality guidelines and regulations), train the field staff members, list the households to be sampled, select the sample, conduct screening and extended interviews in the households, perform all interview and examination procedures in the examination centers, design and carry out quality control procedures, and transmit interview and examination data to NCHS. A complete blood count (CBC) and pregnancy test will be conducted in the MEC laboratory and biological specimens will be shipped to several laboratories in the United States for analysis.

After the listing procedure which identifies households to be potentially included in NHANES, a pre-Advance Letter postcard and an Advance Letter (Attachment 7) are sent to each sampled address informing the occupant(s) that they may be visited by an interviewer. When the interviewer arrives at the home, he or she shows an official identification and briefly explains the purpose of the survey. If the person answering the screener questions has not seen the Advance Letter, a copy is given to him/her. The interviewer then administers the Household Screener Questionnaire Module 1 (Attachment 16 (p Q-2)), solely to determine eligibility. The interviewer next explains the household questionnaires to all eligible participants who are at least 16 years old and informs them of their rights and confidentiality (the same information as appears in the Advance Letter, in case they haven't seen it). For persons under 16 who are eligible, the household questionnaire interview is conducted with a proxy, usually the parent or guardian of the SP. If there is no one living in the household who is over 16, the teenage participant can be interviewed him/herself. If emancipated minors are prohibited by state law to participate in research they will be sampled but not asked to participate (non responders). If convenient for the participant, household questionnaire interview occurs at first contact; or an appointment is made to return to conduct the household questionnaire interviews (Attachment 16 (p Q-29)). After informing the potential respondent about the interview(s) the respondent is

asked to read and sign the Interview Informed Consent Form (Attachment 8), agreeing to participate in the household interview portion of the survey. For participants 7-17 a parent or guardian consents and the child assents.

(Note on informed consent for those unable to read the consent form. If the interviewer discovers the participant to be illiterate or visually impaired, the interviewer reads the entire document to the person in front of a witness. Any questions are answered and if the person agrees, s/he signs the form and completes the interview. If the respondent is unable to sign the form, a witness signature is obtained to indicate that informed consent was received on the part of the participant. The same protocol exists for all consent documents.)

The household interview questions appear in Attachment 16 (p Q-16). The Family Relationship Questionnaire is administered first, followed by the Sample Participant (SP) (p Q-29) and Family questionnaires (p Q-193). The Sample Participant and Family Questionnaires are occasionally tape recorded for quality control purposes. If the interview is selected for taping a box is checked on the interview consent form indicating signed consent. Additionally, verbal consent is recorded on the audio-tape at the beginning of the tape. At the end of the interview the participant is also offered the option to be given the tape to dispose of. This offer and response are also on the audiotape.

The interviewer collects a water specimen from the household after the interview is complete for laboratory analysis. (Attachment 12) When the interview is completed, the interviewer reviews with the participant the examination informed consent brochure (Attachment 8), which contains detailed information about the examination. Each person selected in the household is asked to make an appointment for the examination at the MEC. Those who agree to participate are asked to read and sign consent forms for the examination and the storage of specimens. The interviewer then telephones the field office to make the examination appointments. The interviewer informs the participants that they will receive remuneration as well as reimbursement for transportation expenses and childcare, if necessary.

Participants arrive at the MEC, where the Coordinator (receptionist) verifies identifying information and greets them. Next, the participant is given a pair of disposable pajamas, slippers, and a urine cup before starting their examination. In addition to the Coordinator, the survey team at each center consists of a physician, two dietary interviewers; three certified medical technologists, four health technicians (two of whom are radiological technicians), one phlebotomist, two interviewers and a facility equipment specialist.

The components of the examination are shown in Attachment 3. The examination data collection forms are in Attachment 14. Upon completion of the examination, each examinee is remunerated, as detailed in Section A.9. Some of the medical findings of the examination are given to the examinees before they leave the MEC. Other results are mailed to them later, as results are made available from the laboratories or data graders. The Sexually Transmitted Disease (STD) results are reported to participants by telephone when they call NCHS for the results and provide the personalized password they provided during their MEC examination. Examples of the Reports of Findings given to examinees and a description of the Reports of Findings process are included in Attachment 15.

The examination centers will be open five days each week, with closed days changing on a rotating basis so that appointments will be available on any day of the week. This rotating schedule will also allow collection of dietary recall data across all days of the week, since eating patterns are known to vary for workdays, school days, holidays and weekends.

There will be two examination sessions at the MEC each day, held morning, afternoon, or evening for the convenience of participants. At any given time during the survey, examinations will be conducted at two survey locations simultaneously for eleven months of the year, with breaks of about two weeks at New Years and about two weeks in the summer. This will require field office and household interviewing staff to support two complete examination teams throughout NHANES.

A second dietary recall (DR) interview by telephone will be scheduled 3-10 days after their MEC exam for examinees who had the first DR. A set of measuring guides (including a USDA food model booklet, a ruler, a set of household spoons, and a set of measuring cups and measuring spoons), an appointment reminder card with the date and time of the scheduled interview, and a phone contact number will be given to the participants at the end of their MEC dietary interview. The second DR will be conducted using the USDA's Automated Multiple Pass Method DR system that is also used in the MEC.

After the DR adult sample persons will also receive the Flexible Consumer Behavior Survey (FCBS) via telephone interview. This survey gathers information about nutrition knowledge, attitudes, and beliefs. The respondent has the option of answering the questions during the same phone call as the DR or scheduling a future phone call. Handcards for the FCBS are provided during the MEC DR.

A two question feedback survey will be administered after the end of the Flexible Consumer Behavior Survey (FCBS) telephone follow-up to collect information regarding what motivated respondents to participate in the NHANES survey. This information will be used to help with the further development of NHANES outreach materials and activities

Six months after the examination participants ages 6 and older who had a positive serology test for Hepatitis C infection are contacted by telephone for a brief follow-up interview.

Sample Design

Beginning in 2007 some changes have been made to the domains being oversampled. The primary change will be the oversampling of the entire Hispanic population instead of just the Mexican Americain (MA) population which has been oversampled since 1988. Sufficient numbers of MAs will be retained in the sample design so that trends in the health of MAs can continue to be monitored. Persons 60 and older, black Americans and the low income population will continue to be oversampled. The oversample of pregnant women and adolescents in the survey from 1999-2006 will be discontinued to allow for the oversampling of the Hispanic population. The restrictions imposed by the NHANES examination permit only about 5000 examinations per year. Therefore when a new domain to be oversampled is cycled in another oversampled domain must cycle out.

As with previous NHANES surveys, the design for NHANES is a stratified, multistage probability sample of the civilian non-institutionalized population of the United States. The stages of the sample selection are first: selection of Primary Sampling Units (PSU) (single counties); second: segments within PSU (a block or group of blocks containing a cluster of households); third: households within segments; and fourth: participants within households.

NHANES will have two examination teams that operate continuously over each year of data collection and travel from one PSU to another approximately every 6 weeks. Because of the

time required for setting up, dismantling, relocating, and calibrating equipment, it has been determined from previous NHANES that the MECs must be at each location for at least 4 weeks to be operationally feasible and cost effective. An upper boundary of 8 weeks at each location was established to have an adequate number of PSUs for producing acceptable between-PSU sampling variances. The operational and statistical constraints result in an expected sample of 5,000 examined persons and 15 PSUs per year for NHANES (10,000 persons and 30 PSUs for the years 2007-2008). The target number of participants at each PSU ranges between 235 and 410.

Selection of Primary Sampling Units (PSUs)

PSUs for NHANES 2007-10 have been selected as described below. To determine a probability of selection for each PSU, a measure of size (MOS) based on the most recently available projection of the 2000 Census data is established for each PSU. The MOS reflects the total population of the county, the percent black and the percent total Hispanic. Previous NHANES oversampled blacks and Mexican Americans. The 2007-2008 cycle of NHANES is the first to include an oversample of total Hispanics.

After assignment of the PSU measure of size, the largest counties in terms of the measure of size are included in the sample with certainty. For 2007-2010, there are five certainty PSUs which comprise a total of eight study locations (due to a few large multi-hit PSUs); these are randomly allocated to give two certainty study locations per year. After selection of the certainty PSUs, the remaining non-certainty PSUs are grouped into 13 major strata. The major strata are defined by the four Census regions, metropolitan status (11 metropolitan strata and 2 non-metropolitan strata), and by a race/ethnicity or income indicator. Four PSUs are selected from each major stratum yielding 52 noncertainty PSUs for a four year period and a total of 60 study locations or a four year sample.

To form national estimates for both single and multi-year time periods, the four PSUs within each major stratum are assigned to study years. The ordered 4 PSUs within a major stratum are labeled as A, B, C, and D. A and B, and C and D are paired. One PSU of each pair is randomly selected and randomly allocated to 2007-2008 or 2009-2010. The other PSU of the pair is assigned to the other two year period. For each of the 13 major strata, once the two PSUs of the stratum for 2007-2008 are allocated, a PSU is randomly selected for 2007 or 2008. The two remaining PSUs in each major stratum are assigned to the comparable year in 2009-2010. For example, if B is assigned to 2007, then A is assigned to 2009. If C is assigned to 2008 then D is assigned to 2010. The randomness of both pair-wise selection and annual assignment yields a stratified national sample for the 4 year period 2007-2010; national samples for 2007-2008 and 2009-2010 that are balanced with respect to the stratification variables; and annual samples that are nationally representative and balanced with respect to the stratification variables (but subject to large sampling errors).

Selection of Segments and Households within PSUs

In past cycles of NHANES, to reduce the high cost of screening necessary to locate the sample needed for the minority populations, area segments (consisting of block groups/enumeration districts) were stratified by ethnicity within PSU, and households were sampled at variable rates depending on the concentration of the various ethnic groups within the stratum.

An important change for NHANES 2007-2010 is the replacement of Mexican American sampling domains with Hispanic sampling domains. Since Hispanics are more prevalent in the population

than Mexican Americans, it is no longer necessary or efficient to stratify segments and sample households at variable rates depending on the ethnic concentrations.

The measure of size (MOS) of a segment is calculated in the same way as for PSUs. The actual probability of selection of a segment depends on the MOS of the segment, the MOS of the PSU, and the total MOS of the stratum from which the PSU is selected. The segments are selected with probability proportionate to size, with the MOS based on Census 2000 population data. Research on intraclass correlations and unit costs has indicated that an average of 14 examinees per segment is close to optimum for most statistics in NHANES. Operational constraints require approximately equal number of examined SPs per study location -- about 340 in most locations. The total number of sample segments within the PSUs is expected to be 1,440, an average of 24 per study location. A modification of a sequential sampling procedure known as Perkins Stop Rule is used to efficiently control the number of persons selected for examination at each PSU.

Selection of Sample Persons within Households

The sample of persons is selected by (1) listing all households within sample segments; (2) selecting a sample of households for screening; (3) subsampling persons within households to obtain the desired sample sizes.

The subdomains for subgroup analyses are described in the next section on precision. To achieve desired minimum sample sizes for each domain, sampling rates have been calculated based upon optimum allocation for the subdomain in each race/ethnicity group that requires the highest sampling rate to achieve the desired sample size. All screened persons in the subdomain used for optimum allocation are retained in the sample. The screened persons in other subdomains are subsampled to bring the samples down to the desired levels. The screening rates have been designed to minimize the variability in sampling rates among strata but still achieve the desired precision.

Subsampling is needed to achieve the required sample sizes by age, sex, and race/ethnicity. Experience with NHANES and (Hispanic Health and Nutrition Examination Survey (HHANES) has indicated that response rates are improved when larger sample sizes within households are used. Therefore, the method of subsampling developed will increase the number of sample persons per household. A computer program loaded into the tablet computer carried by the interviewers doing the household screening will tell the interviewers which persons are to become sample persons within each household.

Precision

As a guideline in evaluating the reliability of precision of estimates derived from NHANES surveys, a relative standard error or coefficient of variation (CV) of 30 percent or less was used. Table 4, Attachment 13, B presents the expected distribution of the NHANES sample for 2007 by sampling domains with 15 PSUs. Table 5, Attachment 13, B presents the minimum sample size that is required in each analytic domain to obtain reliable prevalence estimates with a coefficient of variation (CV) of 30 percent and specified design effect. Table 6, Attachment 13, B shows the minimum sample size required in an analytic cell to adequately estimate difference in two proportions with a CV of 30 percent and specified design effect.

Table 5, for example, shows that to estimate a prevalence of 10 percent with CV of 30 percent

and design effect of 1.5, at least 150 examined persons are required. Thus, after only a single year of data collection, one would need to collapse age or gender or race-ethnic domains to achieve the necessary sample size of 150 examinees (see Table 2, Attachment 13, B).

Estimated CVs for expected proportions of 5 percent and 10 percent after two years (n=10,000) and after four years (n=20,000) of data collection are shown in Tables 7a, 7b, 8a and 8b of Attachment 13, B. Based upon a total of approximately 10,000 examined persons in 30 PSUs after two years and assuming a design effect of 1.5, prevalence statistics of 10 percent will have estimated CVs of less than 30 percent (Table 7a of Attachment 13, B) for all specified age, sex, race/ethnicity subdomains except black infants less than 1 year of age, black males ages 40 to 49, black males ages 50 to 59, Hispanic males ages 40 to 49, Hispanic males ages 50 to 59, black females ages 40 to 49, black females ages 50 to 59, Hispanic females ages 40 to 49, and Hispanic females ages 50 to 59. For prevalence of 5 percent or less, estimated CVs are primarily greater than 30 percent (Table 8a of Attachment 13, B) for the specified subdomains. Therefore collapsed analytic categories would be required. After completion of 4 years of data collection, prevalence estimates of 10 percent will result in CVs of 8 to 26 percent (Table 7b of Attachment 13, B). After 4 years, prevalence of 5 percent or less will result in CVs of less than 30 percent for all specified age, sex, race/ethnicity subdomains except black infants less than 1 year of age, black males ages 40 to 49, black males ages 50 to 59, Hispanic males ages 40 to 49, Hispanic males ages 50 to 59, black females ages 40 to 49, black females ages 50 to 59, Hispanic females ages 40 to 49, and Hispanic females ages 50 to 59 (Table 8b of Attachment 13, B).

These tables demonstrate that many domain specific analyses will not be feasible after two years and will require collapsing domains to increase the domain size and produce reliable estimates. However, as the survey continues and completes additional years of data collection, detailed estimates will become possible. As discussed previously, the sample sizes in many sampling domains will not be sufficient to meet the NHANES precision requirements after only 2 years of data collection. Therefore, many of the NHANES analyses will require at least four years of data to produce reliable national estimates. Because each two-year sample is nationally representative, samples may be aggregated to produce national estimates for combinations of 4 or 6 years. For some rare health conditions, six years of data may be required to produce estimates with an adequate precision and reliability.

Estimation

To produce unbiased cross-sectional estimates for the entire civilian, noninstitutionalized population of the United States, the sample data will be inflated to the level of the population from which the sample is drawn. As in previous NHANES, the sampling weight for each sample person will be the product of three factors: the reciprocal of the probabilities of selection (PSU, segment, household, person); an adjustment for nonresponse; and a poststratification factor to make the resulting survey estimates in each age-sex-race-ethnicity category approximately equal to independent control totals from the Current Population Survey (CPS) conducted by the U.S. Bureau of the Census. The population controls will be derived at the midpoint of each survey year. To analyze multiple year samples, sampling weights can either be averaged over the sampled years used or can be readjusted to population controls for the midpoint of the combined years.

Variances for NHANES can be estimated using a number of procedures and software programs. For biannual samples, the number of PSUs is small and the loss of information in pairing the PSUs is substantial. For this reason, a replication technique, such as the jackknife,

is preferred variance estimation. Examples of widely available software programs capable of producing variance estimates from complex surveys include: SUDAAN, which is available from the Research Triangle Institute, WesVar, which is available from Westat, Inc. and STATA. In addition, SAS and SPSS do a limited set of statistical procedures for survey data.

Analytic guidelines are provided on the NHANES website to inform users of the limitations of the data. These are updated and expanded with each data release. The December 2005 version is provided in Attachment 13, C.

Quality Control

Two primary sources of error enter into a survey such as NHANES: sampling error and non-sampling error. Both types of errors can affect the estimates produced from the survey and may lead to a substantial loss in precision in statistical tests. Therefore, an extensive quality control system is a critical element in the operation of NHANES. The objective of the NHANES quality control program is to eliminate measurement errors, to control them, or to measure these errors.

Sampling errors occur when data are collected from a sample of the population rather than a complete census. The errors arise at all stages of sampling from selection of primary sampling units to identification of individual sample persons. Errors in the sampling process may result in non-coverage or incorrect coverage of persons or places. Careful planning and execution of the sampling design at each stage will reduce the sampling error. In surveys like NHANES, selection of PSUs, strata and SPs are done prior to the survey to eliminate bias in the selection process. Although there is no formal quality control plan for the sampling design, various verification checks will be made to ensure the quality and validity of the procedures performed.

Non-sampling errors arise during data collection from sources such as measurement and recording errors in examination, coding of the results, interviewers' mistakes during interviews, recall problems, poor questionnaire design or problems with translations. Since the National Health Examination Surveys (NHES) surveys were conducted in the 1960s, basic quality control procedures have evolved through NHANES I, NHANES II, HHANES, and NHANES III, depending on the content of the examination and technology available. NHANES continues to build on these past experiences. In addition to the procedures used in these previous surveys, NHANES uses an automated sample selection program during the screening phase of the household contact, an automated household interview and an automated data collection system for data entry in the examination phase of the survey with built-in quality control checks and edits. To reduce non-sampling error, NCHS staff are employing the following strategies: field editing, rigorous staff training and periodic retraining with feedback mechanisms, certification of examiners, standard environment, calibration of equipment on regular basis, multiple readings if possible, monitoring of field procedures by headquarters staff, comparison of findings by technicians over time. All laboratory samples are analyzed by certified contract laboratories and standard quality control procedures are used such as blinded split samples and random repeat testing. Data from household questionnaires are carefully entered, verified, validated and edited by experienced field staff and programmers.

If any changes in the survey procedures or data collection instruments are desired after receiving clearance, we will inform OMB of these changes as quickly as possible and at least two weeks before the changes are implemented in a memorandum routed through the NCHS and CDC clearance officers.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Interviewers have access to a variety of materials they use to assist them in sample person nonresponse conversion. In addition to the follow-up letter that is sent to every potential sample person who refuses the interview, examination or both (see Attachment 7), interviewers also have two manuals that serve as a reinforcement to the process: "NHANES At A Glance" and "Obtaining Respondent Cooperation." "NHANES At A Glance" contains articles from newspapers, journals and letters of endorsements to show the sample person. "Obtaining Respondent Cooperation" contains general interviewing approaches and techniques for especially hard-core conversions.

Other methods to maximize response include:

Remuneration of sample persons (A.9)
Payment for transportation/arrangement or free transportation to MEC
Bilingual staff (Spanish)
Interpreters for languages other than Spanish
Advance publicity and contact with/endorsements from community leaders and groups
Post cards prior to advance letter
Sampling multiple individuals in a household
Flexible examination schedule including evenings and weekends
Telephone reminders before scheduled appointments
Intensive follow-up efforts
Videotapes for TV stations
Population specific brochures about the survey
Multimedia presentation on interviewers' tablet computers
Evaluative studies of response where appropriate

If sample persons are apprehensive or reluctant to agree to participate in the examination, there are a number of techniques that can be employed by the interviewer once a reason for non-cooperation has been determined. Some techniques are the same as those used to convince sample persons to participate in the household interview while others are unique to the examination component.

During the interviewing process there are multiple attempts by the interviewer to conduct the screener or an interview. After the first unsuccessful attempt, the interviewer places a Call-Back card, a copy of the advance letter and the screener brochure (Attachment 7) under the door of the potential sample person’s unit.

For sample persons who have scheduled an examination appointment, a reminder notice is mailed one week in advance. Additionally, within forty-eight hours of their examination appointment, all sample persons receive a reminder telephone call. For sample persons who do not have phones, whose phones are not working, or who have not been contacted by phone for some other reason, field contact is made. Field reminders are done in person. If these attempts are unsuccessful, an appointment slip is left at the household for each sample person. If a sample person cancels an examination appointment, recontact is made immediately.

A follow-up letter is sent to sample persons who refuse the household interviews or MEC examinations and to sample persons who have been difficult to contact. The letters are tailored to fit each sample person’s particular circumstance. Examples of letters are included in Attachment 7.

If all else fails to bring the response rates up to the required levels, we request approval for an option to investigate the specific causes of nonresponse, funding permitting.

4. Tests of Procedures or Methods to be Undertaken

Many components of the NHANES field operations have been implemented in past NHANES. This includes operational features such as listing and screening, sections of the questionnaires and components of the examination.

The questionnaire items in NHANES came from many sources that ensured adequate testing of the wording of the questions and selection of appropriate response categories. Many questions were taken from the NHIS core questionnaires. These questions have been tested in the NCHS Questionnaire Design Research Laboratory (QDRL) and then used in the field with thousands of respondents. Additional NHANES questions were derived from standard instruments and tests as well as surveys done by other agencies and organizations. Examples of these are the dietary questions and the mental health module. Still other NHANES questions were taken from previous NHANES surveys.

Examination components have been included in previous NHANES and/or other population based studies (for example, the Cardiovascular Health Study). A criterion for inclusion of examination content for the early years of NHANES was the existence of a standardized procedure for use on NHANES. To incorporate new content in future years of the continuous NHANES, evaluation of objective data collection procedures used in other studies and pilot testing of new procedures concurrent to NHANES data collection will be required. All laboratory methods used in NHANES have been tested and deemed reliable and valid prior to their inclusion in NHANES.

The current continuous operation of NHANES presents unique challenges in pilot testing. All pilot/feasibility testing must be concurrent to the ongoing data collection within the framework of the survey. As protocols and systems are designed and developed, they are fielded. Each examination component is operationalized and evaluated for feasibility of exam room arrangement and procedures, performance of equipment, efficiency, completion times and interaction with the system. Procedures are conducted with trained examiners and actual subjects of the required ages to ensure accurate testing of the components and systems. Standard operating procedures were evaluated for efficiency and coordination of subject flow through the MEC, completion of required exam components, subject cooperation and refusal conversion, staff productivity, and adequacy of facility and supplies. NCHS staff, Westat development staff and consultants participated in the evaluation effort.

2007-2008

Several protocols were tested to be included in the 2007 NHANES after Ethics Review Board and OMB approval. As noted above, all occurred within the current data collection and with the informed consent modified as appropriate for the pilot. Some pilot tests are still in progress. If the pilot test is deemed successful it is proposed for inclusion in 2007. DHANES plans pilot tests only for content fully expected to be successfully implemented on the NHANES survey. A report of each pilot becomes available after completion of the pilot.

Pilot Test of Spirometry Examination

The pilot for the spirometry component took place from April 2 through May 8, 2006. The pilot

allowed us to assess 1) the acceptability of the spirometry protocol with a bronchodilator component, and 2) the integration of the spirometry protocol into the NHANES automated data collection system, and 3) test instructions and scripts used in spirometry and for the bronchodilator administration. Spirometry was conducted using the same instrument and similar protocol as in the previous NHANES surveys with the following new enhancements: a) younger children (ages 6 and 7) underwent testing; and b) children and adults with airway obstruction detected by baseline pulmonary function testing then repeated spirometry after inhalation of a short-acting β2-adrenergic bronchodilator. In addition, because of the small number of persons expected to be eligible for bronchodilator medication during the pilot, one participant each session was asked to take part in a bronchodilator placebo simulation. This participant was given the pre-bronchodilator evaluation, followed by a 10 minute waiting period, concluded with a second lung function test. Unless indicated, the bronchodilator was not administered; instead, a placebo inhaler was administered to those ineligible for the $\beta_2$-adrenergic bronchodilator. The spirometry component was administered in the Mobile Examination Center Spirometry room by two health technicians who took part in a certified NIOSH- training and extensive practice prior to the beginning of the pilot. The physician, also, was trained in the administration of the bronchodilator prior to the study. In order not to increase participant burden, only survey participants 6-79 years who had completed the other components of the regular NHANES examination were eligible to participate.

Of the 258 examined participants at this location, 97 persons participated in the spirometry assessment by the trained health technicians. Of the 97 spirometry participants, 10 persons had partial exams and 87 persons completed the exam. Of the 87 participants who completed spirometry, 9 persons received the bronchodilator and an additional 27 persons participated in the bronchodilator placebo simulation exercise. Of the 161 persons who did not participate in the spirometry assessment, 4 were refusals. The remaining 157 were not able to participate for other reasons, such as not having time, physical limitations, arriving late to the MEC exam or needing to leave early, etc.

The simulation allowed us to fully assess the time requirements, the examination flow consequences, as well as the participant acceptability of performing two lung function tests. Overall the pilot was successful and demonstrated that the Spirometry protocol with the addition of the bronchodilator component was feasible for NHANES. The administration time averaged 20-30 minutes. Findings were sent electronically to expert reviewers (NIOSH) to make the final quality review assessment before the findings were reported. The results for the pilot will not be integrated with the Final Report of Findings but will be independently provided to all pilot participants. Since the conclusion of the pilot, NHANES staff and contractors are currently in the process of making the necessary refinements and enhancements to the protocol and software so the component is ready for January 2007.

Pilot Test of Exhaled Nitric Oxide Measurement (ENO)

The pilot for the exhaled nitric oxide (ENO) component will take place from September 23 through November 3, 2006. All survey participants 6-79 years are eligible to participate in the pilot. The objectives of the pilot are to 1) test instructions and scripts used for the ENO measurement; 2) assess the acceptability of the medical device used for the ENO measurement; 3) gain knowledge in the overall timing of the component and; 4) test the integration of the medical device with the NHANES survey software. The NHANES health technician will conduct the test in the Spirometry room of the Mobile Examination Center using the hand-held Aerocrine NIOX MINO®. The technician will introduce the component, obtain consent or parental permission and then ask about several preconditions that may affect the ENO values. He or she will then coach the participant on how to do the test, monitor the participant's performance for two successful tests, and record the $Fe_{NO}$ (fractional exhaled nitric oxide in parts per billion) results. These steps should take less than 5 minutes. There are no safety exclusions for ENO testing and survey participants will not receive a report of finding.

Pilot Tests of dietary supplement data

Dietary Supplement/Antacid Motivation Questions

Questions were added to the Dietary Questionnaire Section (DSQ) in the Household Interview for 2006 regarding motivations for use of dietary supplements and antacids. Interviewers only ask these motivation questions to all study participants that report taking a dietary supplement or antacid in the past 30 days. The first two questions are open-ended and the interviewer types verbatim the reasons the study participants gives for taking each dietary supplement. The first question collects information on why the study participant is taking a particular supplement (What is the reason or reasons that {you take/SP takes} {PRODUCT NAME}?). If the interviewer determines that a doctor or health care professional did tell the study participant to take the dietary supplement, a follow-up question is asked (For what reason or reasons did the doctor or other health professional tell {you/SP} to take {PRODUCT NAME}?). A categorical question was added to the DSQ-Antacid Section of the Household Interview to determine if the antacid taken in the past 30 days was used as an antacid, a calcium supplement or both.

Based on answers given by study participants for the open-ended dietary supplements pilot questions, categorical questions were developed. The categories created were based on the common reasons that people gave for taking dietary supplements. The antacid pilot study categorical question will be kept the same for NHANES 2007-2008. Many antacids contain a high level of calcium, and therefore can contribute heavily to the total daily intakes of calcium. This question is important so that we can be aware of the amount of people that take antacids for calcium. Eighty-nine percent of study participants in the pilot reported taking the antacid as an antacid, 2% reported taking it as a calcium supplement, 7% reported taking it for both and about 2% reported not taking it for any of those reasons. Since publicly available data on reasons for supplement use are limited, the questions are very helpful and also needed in the research of dietary supplements. The research that is available on why people take supplements seems to rely on previously specified categories. Improved understanding of the reasons that people take supplements along with the supplements that they report taking will be very useful to the nutrition community in order to better target public health messages to people possibly overusing supplements (e.g. with excessive mineral intakes) as well as to people whose nutritional status would be improved by taking dietary supplements.

24-Hour Dietary Supplement and Antacids

The objective of this pilot test was to collect data on dietary supplement and antacid use as part

of the 24-hour dietary recall interview in the Mobile Examination Center (MEC). NHANES currently collects data on study participants' use of dietary supplements, in the past 30 days, during the Dietary Supplements Section (DSQ) in the Household Interview. Asking about dietary supplement use as part of the 24-hour dietary recall interview will provide researchers the ability to combine 24-hour dietary nutrient intake from foods, currently collected in the 24-hour dietary food recall, with 24-hour nutrient intake from dietary supplements. This will allow more precise estimates of total nutrient intake. The target group for the questions is the examined sample, all ages, identical to the target group for the 24-hour dietary food recall. Dietary supplement and antacid questions were added to the MEC 24-Hour Dietary Recall component and the Phone Follow-up 24-Hour Dietary Recall component. Interviewers first verified whether or not the respondent had taken the dietary supplement that was reported during the DSQ Household Interview during a 24-hour time period (midnight to midnight). If the respondent verifies that they had taken the dietary supplement during the 24-Hour time period, the interviewer asks how much was taken. After going through and verifying all dietary supplements that were reported during the DSQ Household Interview, respondents are asked if they had taken any other dietary supplements during the 24-hour time period. If the respondent answers yes, then interviewers collect information on the name of the supplement and respondents are asked how much they took. The same process is repeated for non-prescription antacids. If dietary supplements were not reported during the DSQ Household Interview, then respondents are asked if they have taken any during the 24-Hour time period.

The pilot study helped to develop the final protocol to be used in NHANES 2007-2008. Some changes were made to the protocol based on what worked with the pilot study, such as rewording of questions for easier flow and more probes to help interviewers collect better quality data. Since most of the supplements people are taking have already been captured during the Household Interview and imported into the 24-hour dietary recall interview component, the interviewers didn't have to manually record too many new supplements. Of the 325 respondents in the pilot study, 8% in the MEC 24-hour dietary recall interview and 6.6% in the phone follow-up 24-hour dietary recall interview reported taking a supplement that was not reported in the DSQ Household Interview. This new component had added minimal extra time, with the average time for the component being about 1 minute.

## Pilot Test of Flexible Consumer Behavior Survey (FCBS)

A pilot study is scheduled September 26 through November 30, 2006 to evaluate the operational feasibility of the telephone interview portion of the FCBS. A ten-day letter had been submitted to OMB at the time this document was prepared. The pilot study will integrate the new phone follow up questionnaire with the existing NHANES automated data collection system. It will be conducted following the day 2 dietary phone follow up interview. Evaluation will include: (1) observation and evaluation of performance of the questions by NCHS and home office staff of the data collection contractor; (2) review of the data collected to evaluate the quality and completeness of the data and (3) evaluation of details of the protocol . NCHS and Westat staff will periodically observe data collection. Summary data will be discussed with the Economic Research Service, the NHANES FCBS questionnaire sponsor.

## Pilot Test of Food Stamp and WIC administration record linkage

A feasibility/pilot test linking NHANES records to Food Stamp and WIC Program administrative records is planned for late CY 2006 based on data from one NHANES location from NHANES 1999-2005. If successful this may become part of the protocol for the NHANES 2007-2008

cycle of NHANES. A 'ten-day' letter to OMB will be generated when a detailed protocol is developed.

Pilot Testing for 2009-2010

All pilot/feasibility testing must be concurrent to the ongoing data collection within the framework of the survey. DHANES proposes continuing to pilot test the procedures for 2009-2010 as we have done in 2006 for 2007-2008. We plan to start the piloting and developing methods in the spring of 2007. Currently planned are two methodological studies. One involves validation of oral health questions and an examination related to periodontal disease. The second is a validation study of self reported pubertal maturation questions. NHANES will continue to request permission to conduct pilot and methodological studies through the use of the 10-day letter mechanism.

Nonresponse Investigation

Nonresponse investigations under DHHS task order contracts or other contract mechanisms may be necessary should nonresponse rates make that advisable. Reliable estimates for subpopulations of interest would be impaired if nonresponse in those subpopulations were unacceptably high. Although NHANES uses many time-consuming and costly mechanisms to increase response rates, separate scientific investigations of the causes of nonresponse and possible remedies may be needed and approval for such options is hereby requested. Details of any such investigations that involve public participation will be submitted to OMB as required in the terms of clearance.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

1) The following person was consulted in the statistical aspects of the design of the NHANES:

Lester R. Curtin, Ph.D.
Mathematical Statistician
Division of Health and Nutrition Examination Surveys
National Center for Health Statistics
Centers for Disease Control and Prevention
Phone: 301-458-4172

2) The following person is responsible data collection activities:

Clifford L. Johnson
Director, Division of Health and Nutrition Examination Surveys
National Center for Health Statistics
Centers for Disease Control and Prevention
Phone: 301-458-4292

3) The following person is responsible for analysis of the NHANES data:

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