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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention [30Day-17-0950]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic,

mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

The National Health and Nutrition Examination Survey (NHANES), (OMB No. 0920-0950, expires 12/31/2017) - Revision - National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability; environmental, social and other health hazards; and

determinants of health of the population of the United States.

The National Health and Nutrition Examination Survey (NHANES) have been conducted periodically between 1970 and 1994, and continuously since 1999 by the National Center for Health Statistics, CDC. Annually, approximately 14,410 respondents participate in some aspect of the full survey. Up to 13,104 additional persons might participate in tests of procedures, special studies, or methodological studies. Participation in NHANES is completely voluntary and confidential. A three-year approval is requested.

The data collected through NHANES allows for the production descriptive statistics which measure the health and nutrition status of the general population. Through the use of physical examinations, laboratory tests, and interviews NHANES studies the relationship between diet, nutrition and health in a representative sample of the civilian noninstitutionalized population of the United States. NHANES monitors the prevalence of chronic conditions and risk factors. NHANES data are used to produce national reference data on height, weight, and nutrient levels in the blood. NHANES also seeks to be responsive in exploring emerging public health issues and new health related technologies. Results from more recent NHANES can be compared to findings reported from previous surveys to monitor changes in the health of the U.S. population over time. NHANES collects

personal identification information. Participant level data items will include basic demographic information, name, address, social security number, Medicare number and participant health information to allow for linkages to other data sources such as the National Death Index (OMB No. 0920-0124, expires 10/31/2016 and data from the Centers for Medicare and Medicaid Services (CMS).

A variety of agencies sponsor data collection components on NHANES. To keep burden down, NCHS cycles in and out various components. Health interviews are conducted in the participants' household. Physical exams are conducted in the Mobile Examination Center (MEC). The 2017-2018 NHANES physical examination includes the following components: anthropometry (all ages), 24-hour dietary recall (all ages), physician's examination (all ages, blood pressure is collected here), and oral health examination (ages 1 and older, body composition using Dual X-ray Absorptiometry (DXA) exam (ages 8-59) and hearing (ages 6-19 and 70+ (and above)). The hearing age range for 2017-18 is a modification (The 2015-16 hearing age range was 20-69 years).

While at the examination center additional interview questions are asked (6 and older), a second 24-hour dietary recall (all ages) is scheduled to be conducted by phone 3-10 days later. In 2017 we plan to add a liver elastography

(ultrasound) exam for participants 12 years and older. A set of alcohol and liver-related questions, and a hip measurement will also be added to complement the liver exam. The age range for liver-related blood test (serum ferritin) already collected in NHANES is being expanded from female participants 12-49 to all participants 12 years and older. The existing collection of serum ferritin in children 1-5 years will continue. We will cycle bone density for hip and spine back into the (DXA) exam for (ages 50+). The Osteoporosis questionnaire will also cycle back into NHANES to complement the changes to the DXA exam. These questions will be asked of participants 50+.

NHANES plans to conduct a blood pressure methodology study. The study population will be NHANES participants aged 6 and older who agree to come to the Mobile Examination Center (MEC).

The bio-specimens collected for laboratory analytes include urine, blood, vaginal and penile swabs, and household water collection. Serum, plasma and urine specimens are stored for future testing, including genetic research, if the participant consents. NHANES 2017-18 plans to add the following lab tests: three Phthalates in urine (ages 3+); nine urinary flame retardants in urine (ages 3+); one insect repellent in urine (ages 3+); one volatile organic compound (VOC) metabolite in urine (ages 3+); eighteen tobacco biomarkers in urine (ages 3+); two metals in urine (ages 3+); vitamin C in serum (ages 6+);

vitamins A, E, and carotenoids in serum (ages 6+); Unsaturated Iron Binding Capacity (UIBC)/Total Iron Binding Capacity (TIBC) in serum (ages 12+); congenital cytomegalovirus (CMV) in sera (ages 1-5); and a test in urine for Mycoplasma genitalium (ages 14-59).

In addition metals in whole blood are changing from a one-half sample to a full sample (ages 1+). Polycyclic Aromatic Hydrocarbons (PAHs) are being discontinued in the smoker oversample subgroup, however testing will continue in a 1/3 subsample of general NHANES participants.

The 2017-18 survey will also bring back the Flexible Consumer Behavior Survey Phone follow-Up questionnaire for participant ages 1+. This takes place in the home after the second dietary recall is completed.

The following major examination or laboratory items, that had been included in the 2015-2016 NHANES, were cycled out for NHANES 2017-2018: pubertal maturation, Oral Glucose Tolerance Test (OGTT), oral Human Papilloma Virus (HPV) rinse, Sagittal Abdominal Diameter (SAD), dental fluorosis assessment, dental fluorosis imaging (DFI), plasma, urine and water fluoride, Apo B analysis, three metals in serum and three hormones and binding proteins.

Most sections of the NHANES interviews provide self-reported information to be used either in concert with specific

examination or laboratory content, as independent prevalence estimates, or as covariates in statistical analysis (e.g., socio-demographic characteristics). Some examples include alcohol, drug, and tobacco use, sexual behavior, prescription and aspirin use, and indicators of oral, bone, reproductive, and mental health. Several interview components support the nutrition monitoring objective of NHANES, including questions about food security and nutrition program participation, dietary supplement use, and weight history/self-image/related behavior.

In 2017-2018, we also plan to implement electronic consent procedures in NHANES. The consent for birth certificate linkage that had been included in previous NHANES will be dropped from NHANES 2017-2018. The survey may conduct a Vaccination Providers' Records Check project with an emphasis on Human Papilloma Virus (HPV), an Ambulatory Blood Pressure Methodology (ABPM) study, test questions related to Chronic Kidney Disease (CKD), adopt digital imaging technology to enhance the existing collection of dietary supplement information, implement multi-mode screening, conduct specimen collection for liver-related DNA markers, and cycle back in consent to store DNA, if resources permit, in the current or in a future cycle of NHANES.

There is no cost to respondents other than their time. Total burden hours requested is 79,894.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)	Total Burden Hours
Individuals in households	NHANES Questionnaire	14,410	1	2.5	36,025
Individuals in households	Blood Pressure Methodology Study Phase 1	1,404	1	30/60	702
Individuals in households	Blood Pressure Methodology Study Phase 2	2000	1	30/60	1000
Individuals in households	Flexible Consumer Behavior Survey Phone Follow-Up	5,000	1	20/60	1,667
Individuals in households	Developmental Projects & Special Studies	3,500	1	3	10,500
Individuals in households	Wearable Device Projects	1,200	1	25	30,000

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