

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-14-0950]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to LeRoy Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

The National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0950, expires 11/30/2015)—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 Surveys (NHANES) have been conducted periodically between

1970 and 1994, and continuously since 1999 by the National Center for Health Statistics, CDC. Annually, approximately 15,613 respondents participate in some aspect of the full survey. About 10,735 respondents complete the screener for the survey. About 209 respondents complete the household interview only. About 4,669 respondents complete both the household interview and the Mobile Exam Center (MEC) examination. Up to 2,500 additional persons might participate in tests of procedures, special studies, or methodological studies (Table 1). Participation in NHANES is completely voluntary and confidential. A three-year approval is requested.

NHANES programs produce 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 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. 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. NCHS 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 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. The 2015-2016 NHANES physical examination includes the following components: oral glucose tolerance test (ages 12 and older), anthropometry (all ages), 24-hour dietary recall (all ages), physician's examination (all ages, blood pressure is collected here), oral health examination (ages 1 and older), hearing (ages 20-59), dual X-ray absorptiometry (total body composition ages 6-59 and osteoporosis, vertebral fractures and aortic calcification ages 40 and older).

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, and an appointment is made to return to the MEC to begin a 24-hour urine collection (one-half sample of ages 20-69). In 2014, a 24-hour urine collection was added to the NHANES protocol to better understand sodium intake and provide a population baseline for use in monitoring trends in sodium intake in the future. In 2015, FDA is scheduled to implement a plan to promote broad, gradual reduction of added sodium in the food supply. One half of those successfully completing the initial collection will be asked to complete a second 24-hour urine. After completing the 24-hour urine participants are asked to provide 2 home urine collections (first morning and an evening) and mail them back. The urines collected in the morning and evening will be compared to the 24-hour urine collection.

The bio-specimens collected for laboratory tests include urine, blood, vaginal and penile swabs, oral rinses and household water collection. Serum, plasma and urine specimens are stored for future testing if the participant consents.

The following major examination or laboratory items, that had been included in the 2013-2014 NHANES, were cycled out for NHANES 2015-2016: physical activity monitor, taste and smell component and upper body muscle strength (grip test).

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.

NHANES data users include the U.S. Congress; numerous Federal agencies such as other branches of the Centers for Disease Control and Prevention, the National Institutes of Health, and the United States Department of Agriculture; private groups such as the American Heart Association; schools of public health; and private businesses. There is no cost to respondents other than their time.

TABLE 1—ESTIMATED ANNUALIZED BURDEN HOURS

Type of Respondent	Form	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Individuals in households	NHANES Questionnaire	15,613	1	2.5	39,033
Individuals in households	Special Studies	2,500	1	3	7,500
Total	46,533

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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[30Day-14-0889]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to 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

Using Traditional Foods and Sustainable Ecological Approaches for Health Promotion and Diabetes Prevention in American Indian/Alaska Native Communities (OMB No. 0920-0889, exp. 6/30/2014)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 2008, the CDC's Native Diabetes Wellness Program (NDWP), in consultation with American Indian/Alaska Native (AI/AN) tribal elders, issued a funding opportunity

announcement (FOA) entitled, "Using Traditional Foods and Sustainable Ecological Approaches for Health Promotion and Diabetes Prevention in American Indian/Alaska Native Communities." The Traditional Foods program was designed to build on what is known about traditional ways in order to inform culturally relevant, contemporary approaches to diabetes prevention for AI/AN communities. The program supports activities that enhance or re-introduce indigenous foods and practices drawn from each grantee's landscape, history, and culture. Example activities include the cultivation of community gardens, organization of local farmers' markets, and the dissemination of culturally appropriate health messages through storytelling, audio and video recordings, and printed materials. In addition, the program promotes physical activity initiatives, provides social support for healthy lifestyles, and supports collaboration with other agencies and programs.

Seventeen (17) tribal organizations received cooperative agreement funding under the initial FOA. Sixteen tribal organizations applied for a one-year extension that ends September 30, 2014.

CDC currently collects information from awardees about the activities supported with Traditional Foods funding. Each awardee submits a shared data elements (SDE) report to CDC through a Web-based interface. Information has been collected twice per year, in spring and fall. CDC anticipates that the spring 2014 report will be submitted to CDC under the current OMB clearance (OMB No. 0920-0889, exp. 6/30/2014). In order to receive a final report in the fall of 2014, CDC is requesting a six-month continuation of OMB approval, through approximately December 31, 2014. Because of the variety of food- and lifestyle-related programs that take place in the late spring, summer, and early fall, CDC wants to ensure complete and

accurate reporting of awardee activities conducted the final months of cooperative agreement funding.

There are no proposed changes to the data collection instrument, data collection methodology, or the estimated burden per response. The SDE will continue to be submitted to CDC using Survey Monkey, an electronic Web-based interface. The estimated burden per response is two hours. Each grantee will receive a personalized advance notification letter, followed by an email with a link to the Survey Monkey site. Changes to be implemented in this Revision request include: 1) A reduction in the number of respondents, from 17 to 16, 2) a change in the frequency of reporting (only one SDE report will be received during the six-month extension period), and 3) discontinuation of the one-time retrospective data collection that was part of the initial three-year clearance request.

CDC will continue to use the SDE reports to compile a systematic, quantifiable inventory of activities, products, and outcomes associated with the Traditional Foods program. The SDE also allow CDC to analyze aggregate data for improved technical assistance and overall program improvement, reporting, and identification of outcomes; allow CDC and grantees to create a comprehensive inventory/resource library of diabetes primary prevention ideas and approaches for AI/AN communities and identify emerging best practices; and improve dissemination of success stories.

Respondents will be 16 Tribes and Tribal organizations that receive funding through the Traditional Foods program. Participation in this information collection is required for Traditional Foods program awardees. There are no costs to respondents other than their time.

The total estimated annualized burden hours are 32.