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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-17-16AJE]

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 NHANES Longitudinal Study - Feasibility Component - New - 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. Under this authorization, NCHS has conducted the National Health and Nutrition Examination Surveys periodically between 1970 and 1994, and continuously since 1999 (NHANES, see OMB Control No. 0920-0237 and OMB Control No. 0920-0950). The NHANES survey is based on a cross-sectional design employing a stratified, multistage probability sample. Information collection methods include interviews and direct physical measurements. NCHS uses NHANES data to produce descriptive statistics on the health and nutrition status of the general population, including estimates of the prevalence of numerous chronic diseases and conditions.

To enhance the information collected through NHANES, NCHS has initiated planning activities for a future NHANES Longitudinal Study, with a target starting date for data collection in 2020. A longitudinal cohort design is needed to examine changes in participants' health conditions, their utilization of healthcare since the time of their original NHANES exam, and the long-term impact of risk factors on the development of morbidity. Participants in the NHANES Longitudinal Study will be individuals who participated in NHANES between 2007 and 2014. The survey's extensive baseline

data on health conditions, nutritional status, and risk behaviors, analyzed in conjunction with information from a longitudinal cohort, will support the estimation of incidence for a wide range of chronic conditions as well as tracking of progress on national goals for prevention.

The NHANES Longitudinal Study planned for 2020 will be the first nationally representative cohort in more than two decades. The last cohort of this type was the NHANES Epidemiologic Follow-up Studies (OMB Control No. 0920-0218) conducted in 1984-1985, 1988, and 1992-1993. Since then, response rates in major federal surveys have declined and obtaining cooperation from the household population has become more difficult. Therefore, before attempting to launch a full scale data collection effort among all examined adults from NHANES 2007-2014, we propose to conduct a feasibility study in 2017-2018 to determine whether previously examined participants can be successfully traced, interviewed, and examined.

The Feasibility Component of the NHANES Longitudinal Study is comprised of two elements: 1) a field feasibility test for the core interview and examination module of the NHANES Longitudinal Study; and 2) a series of targeted methodological tests of additional components and procedures. Information will be collected to evaluate the operational feasibility of the core module and to assess the performance of these components

administered in the home setting. The core module currently planned for the NHANES Longitudinal Study will focus on chronic conditions including obesity, diabetes, cardiovascular disease, and kidney disease.

An annual sample of 400 respondents (total of 800 participants over the two-year period) will be selected from the 2007-2014 NHANES examinees (20 years and older) to participate in the field feasibility test. Of these, we expect approximately 11% to be deceased prior to the re-contact, resulting in a target annual sample of 356 living examinees and 44 decedent proxy interview respondents.

As part of the preparation efforts for a longitudinal study of all examined adults from NHANES 2007-2014, up to 375 additional persons per year (750 participants over the two-year period) may be asked to participate in targeted tests of proposed methods and procedures such as bio-specimen collections, cognitive testing for questions, or protocol tests for additional exam components. These targeted tests will only occur if resources permit and if tracing and participation in the field feasibility test is successful. These targeted methodological studies will be conducted with volunteers who are not from the NHANES cohort, or past NHANES participants who are not part of the potential NHANES Longitudinal Study sample (for example, past NHANES participants from the 1999-2006 cycle).

The estimated average burden for the field feasibility test is 84 minutes per respondent (1.5 hours per respondent for 356 living participants and 35 minutes per respondent for 44 proxy of deceased participants, annually). The average burden for the targeted methodological study respondents is one hour.

Demographic information such as name, address, phone numbers, and social security number collected in the baseline NHANES will be used to locate the sampled 800 field feasibility test participants (annual sample of 400). Prior to the re-contact, a review of the NHANES linked mortality files will be conducted to assist in determining the vital status of sampled participants.

Trained Health Representatives will visit the sampled participants at home to conduct an in-person interview and a health examination. Information that will be collected through the interview includes health status and medical conditions, health care services, health behaviors, and sociodemographic characteristics. In addition, permission for collecting hospital discharge data, including diagnoses at discharge and procedures performed during hospitalization will be obtained during the interview.

Following the interview, a health examination will be conducted as part of the home visit. The respondent's weight, waist circumference, and sitting blood pressure will be

measured, and a monofilament assessment will be conducted for neuropathy. In addition, blood and urine will be collected. Examples of laboratory tests planned include hemoglobin A1c from the blood specimen, and albumin and creatinine from the urine collection. This proposed project will assess the feasibility of conducting these tests and procedures in the home setting.

A proxy interview will be conducted via telephone for sampled participants who died prior to the re-contact. Information on medical conditions and overnight hospital stays since baseline will be collected.

Although permission will be sought from all field feasibility test participants, hospitalization records will be obtained only for 120 participants annually (240 participants over the two-year period) to evaluate the record retrieval protocol for the study cohort among different medical facilities. An average of three hospital stays per person is anticipated among this cohort, therefore, an estimated 360 requests (120 persons X 3 stays) will be made annually. The estimated burden for hospital record provider is 20 minutes per record.

OMB approval is requested for two years to conduct the feasibility component of the NHANES Longitudinal Study. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden

hours are 1,055.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)
2007-2014 NHANES examinees, and proxies of deceased 2007-2014 NHANES examinees	Field feasibility test registration form - contact confirmation and scheduling preference	400	1	15/60
2007-2014 NHANES examinees	Field feasibility test home visit	356	1	1
2007-2014 NHANES examinees	Field feasibility test home urine collection	356	1	15/60
Proxies of deceased 2007-2014 NHANES examinees	Field feasibility test decedent proxy interview	44	1	20/60
Hospital record providers	Field feasibility test hospital records form	360	1	20/60
Adult volunteers (non-field feasibility test	Targeted methodological studies	375	1	1

participants)				
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Leroy A. Richardson
Chief, Information Collection Review Office
Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

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