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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-16-16AJE; Docket No. CDC-2016-0043]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the proposed National Health and Nutrition Examination Survey (NHANES) Longitudinal Study – Feasibility Component. This project will provide a logistical test of proposed survey procedures along with contact, interview, and examination rates for a sample of previously examined NHANES participants. The information obtained will be

used to determine the feasibility of conducting future follow-up surveys.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0043 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

FOR FURTHER INFORMATION CONTACT: Leroy A. Richardson, the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74,Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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; (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; and (e) estimates of capital or start-up costs and costs of operation,

maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

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, the National Health and Nutrition Examination Surveys (NHANES) have been conducted periodically between 1970 and 1994, and continuously since 1999 by NCHS, CDC to produce descriptive statistics on the health and nutrition status of the general population based on direct physical measurements.

The increasing prevalence of obesity and chronic diseases, including diabetes, cardiovascular and kidney diseases, is an important public health issue. If feasible, re-contacting past NHANES participants could provide information about changes in their health condition, exposure to risk factors, and utilization of healthcare since the time of their original NHANES exam, thereby making it possible to estimate the incidence of various chronic conditions. The survey's extensive baseline data on health conditions, nutritional status, risk behaviors, and environmental exposures could further allow the identification and monitoring of the impact of these factors on the participant's current health status. Planning activities for a future longitudinal study of all NHANES examined adults from 2007-2014 have been initiated. This study - the NHANES Longitudinal Study, targeted to start data collection in 2019 or 2020, will provide data to estimate the incidence of selected health outcomes in the U.S. population and relative risk related to other baseline data. The data collection effort proposed in

this announcement is only for the Feasibility Component of the NHANES Longitudinal Study. The interview and examination content proposed in the Feasibility Component represents the core module of the future NHANES Longitudinal Study.

Not since the NHANES I Epidemiologic Follow-up Study (NHEFS), which was also conducted by NCHS, has there been a follow-up of a nationally representative cohort to assess the relations between baseline clinical, nutritional, and behavioral factors to subsequent morbidity and mortality. While NCHS has prior experience conducting the follow-up of the NHANES I cohort in 1982-1984, more than 30 years has passed. 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 conducting a feasibility study (the NHANES Longitudinal Study – Feasibility Component) to determine whether previously examined participants can be successfully traced, interviewed, and examined. The proposed Feasibility Component is comprised of two elements: 1) a field feasibility test for the core module of the NHANES Longitudinal Study; and 2) a series of targeted methodological tests of additional components and procedures.

An annual sample of 400 respondents (total of 800

participants over the 2-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 deceased 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 2-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 paid volunteers 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).

Participation in the field feasibility test and the targeted methodological studies is completely voluntary and confidential. The estimated average burden for the field feasibility test is 42 minutes per respondent (1.5 hours per respondent for 356 living participants and 40 minutes per

respondent for 44 proxy of deceased participants, annually). The average burden for the targeted methodological study respondents is 1 hour. A two-year approval is requested.

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 NHANES-linked mortality files will be conducted to assist in determining the vital status of sampled participants.

Trained interviewers 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 may 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 examination 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 2-year period) to evaluate the record retrieval protocol for the study cohort among different medical facilities. An average of 3 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.

There is no cost to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per	Average Burden per	Total Burden Hours

			respondent	Response (in hours)	
2007-2014 NHANES examinees	Field feasibility test initial contact and appointment scheduling form	400	1	20/60	133
2007-2014 NHANES examinees	Field feasibility test home visit	356	1	1	356
2007-2014 NHANES examinees	Field feasibility test home urine collection	356	1	10/60	59
Proxy of deceased 2007-2014 NHANES examinees	Field feasibility test deceased proxy interview	44	1	20/60	15
Hospital record providers	Field feasibility test hospital records form	360	1	20/60	120
Adult volunteers (non-field feasibility test participants)	Targeted methodological studies	375	1	1	375
Total					1058

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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