

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**

Factors Influencing the Transmission of Influenza—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The National Institute for Occupational Safety and Health

(NIOSH) is authorized to conduct research to advance the health and safety of workers under Section 20(a)(1) of the 1970 Occupational Safety and Health Act.

Influenza continues to be a major public health concern because of the substantial health burden from seasonal influenza and the potential for a severe pandemic. Although influenza is known to be transmitted by infectious secretions, these secretions can be transferred from person to person in many different ways, and the relative importance of the different pathways is not known. The likelihood of the transmission of influenza virus by small infectious airborne particles produced during coughing and breathing is particularly unclear. The question of airborne transmission is especially important in healthcare facilities, where influenza patients tend to congregate during influenza season, because it directly impacts the infection control and personal protective measures that should be taken by healthcare workers.

The purpose of this study is to gain a better understanding of the production of infectious aerosols by patients with influenza, and to compare this to the levels of biomarkers of influenza infection in the blood of these patients. To do this, airborne particles produced by volunteer subjects with influenza will be collected and tested for

influenza virus, and the levels of influenza infection-associated biomarkers will be measured in blood samples from these subjects.

Volunteer adult participants will be recruited by a test coordinator using a poster and flyers describing the study. Interested potential participants will be screened verbally to verify that they have influenza-like symptoms and that they do not have any medical conditions that would preclude their participation. Qualified participants who agree to participate in the study will be asked to read and sign an informed consent form, and then to complete a short health questionnaire. After completing the forms, the participant's oral temperature will be measured and two nasopharyngeal swabs and five milliliters of blood will be collected. The participant then will be asked to cough repeatedly into an aerosol particle collection system, and the airborne particles produced by the participant during coughing will be collected and tested.

The study will require 40 volunteer test subjects each year for three years, for a total of 120 test participants. NIOSH intends to seek a three-year OMB approval to conduct this information collection. There are no costs to respondents other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Potential participant .....	Initial Verbal Screening .....	240	1	3/60	12
Qualified participant .....	Informed consent form .....	120	1	15/60	30
Qualified participant .....	Health questionnaire .....	120	1	5/60	10
Qualified participant .....	Medical Testing .....	120	1	40/60	80
<b>Total .....</b>	.....	.....	.....	.....	<b>132</b>

**Leroy A. Richardson,**  
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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](mailto: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 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  $\times$  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 participants).	Targeted methodological studies .....	375	1	1

**Leroy A. Richardson,**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–39]

#### Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare and Medicaid Services (CMS) is requesting that an information collection request (ICR) related to the Medicare and Medicaid Programs: Conditions of Participation for Home Health Agencies (HHAs) and Supporting Regulations at 42 CFR part 484, be processed under the emergency clearance process associated with 5 CFR 1320.13(a)(2)(i). Public harm is reasonably likely to ensue if the normal, non-emergency clearance procedures are followed. The approval of this information collection package is necessary because in the absence of

such approval CMS will be unable to effectively enforce these essential health and safety requirements. Among other things, CMS will be unable to enforce requirements that HHAs must provide a notice of rights to each patient, assure the proper training of home health aides before those aides provide hands-on care to patients, and disclose the names and addresses of all individuals with an ownership or management position so that we can assure that those with a history of fraud are not involved in HHA operations. Being unable to enforce these rules would harm patient health and safety, as well as create risks to the integrity of the Medicare and Medicaid programs.

Under the PRA, federal agencies are required to publish notice in the **Federal Register** concerning each proposed ICR. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this ICR including the necessity and utility of the proposed ICR for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by April 3, 2017.

**ADDRESSES:** When commenting, please reference the document identifier (CMS–R–39) or OMB control number (0938–0365). To be assured

consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS–R–39/OMB Control Number 0938–0365, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786–1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786–1326.

**SUPPLEMENTARY INFORMATION:**