DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-20-1208]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled The National Health and Nutrition Examination Survey (NHANES) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on December 6, 2019 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(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, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.
Proposed Project
Developmental Projects to Improve the National Health and Nutrition Examination Survey and Related Programs, (OMB Control No. 0920-1208 Exp. 12/31/2020) – 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 Division of Health and Nutrition Examination Surveys (DHNES) has conducted national surveys and related projects periodically between 1970 and 1994, and continuously since 1999.

The mission of DHNES programs is to produce descriptive statistics which measure the health and nutrition status of the general population. The continuous operation of DHNES programs presents unique challenges in testing new survey content and activities, such as outreach or participant screening.

In 2023 and beyond, NHANES may need to implement changes to the survey such as sample design, outreach activities,
procedures, content, protocols, methods and settings in which the survey is conducted. The survey may also need to collaborate more closely with other public health surveys and programs, both within NCHS/CDC and with outside organizations. Such changes may be needed to respond to declines in response rate, adapt to changes in technology and address future public health needs. To prepare for such change, the program may need to do more testing than in past cycles. This request includes an increase in number of participants and burden hours for Developmental Projects & Focus Group activities. It also expands the types of participants covered by this generic request to include “current or past participants of other NCHS surveys/programs/projects” and “individuals eligible to be participants of other NCHS surveys/programs/projects, but who did not actually screen in”.

This generic revision request covers developmental projects to help evaluate and enhance DHNES existing and proposed data collection activities to increase research capacity and improve data quality. The information collected through this Generic Information Collection Request will not be used to make generalizable statements about the population of interest or to inform public policy; however, methodological findings from these projects may be reported.

The purpose and use of projects under this NHANES generic clearance would include developmental projects necessary for
activities such as testing new procedures, equipment, technology and approaches that are going to be folded into NHANES or other NCHS programs; designing and testing examination components or survey questions; creating new studies, including biomonitoring and clinical measures; creating new cohorts, including a pregnancy and/or a birth – 24 month cohort; testing of the cognitive and interpretive aspects of survey methodology; feasibility testing of proposed new components or modifications to existing components; testing of human-computer interfaces/usability; assessing the acceptability of proposed NHANES components among likely participants; testing alternative approaches to existing NHANES procedures, including activities related to improving nonresponse; testing the use of or variations/adjustments in incentives; testing content of web based surveys; testing the feasibility of obtaining bodily fluid specimens (blood, urine, semen, saliva, breastmilk) and tissue sample (swabs); testing digital imaging technology and related procedures (e.g., retinal scan, liver ultrasound, Dual-energy X-ray absorptiometry (DEXA), prescription and over-the-counter dietary supplements bottles); testing the feasibility of and procedure/processes for accessing participant’s medical records from healthcare settings (e.g., hospitals and physician offices); testing the feasibility and protocols for home examination measurements; testing survey materials and
procedures to improve response rates, including changes to advance materials and protocols, changes to the incentive structure, introduction of new and timely outreach and awareness procedures including the use of social media; conducting crossover studies; creating and testing digital survey materials; and conducting customer satisfaction assessments.

The types of participants covered by the NHANES generic may include current or past NHANES participants; family or household members of NHANES participants; individuals eligible to be participants in NHANES, but who did not screen into the actual survey; convenience samples; volunteers; subject matter experts or consultants such as survey methodologist, academic researchers, clinicians or other health care providers; NHANES data or website users; members of the general public or individuals abroad who would be part of a collaborative development project or projects between NCHS and related public health agencies in the U.S. and/or abroad.

The type of participants involved in a given developmental project would be determined by the nature of the project. The details of each project will be included in the specific GenIC submissions. Participation is voluntary and confidential. There is no cost to respondents other than their time. We are requesting a three-year approval, with 59,465 annualized hours of burden.
### Estimated Annualized Burden Hours

<table>
<thead>
<tr>
<th>Type of Respondents</th>
<th>Form Name</th>
<th>Number of Respondents</th>
<th>Number of Responses per respondent</th>
<th>Average Burden per Response (in hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals or households</td>
<td>Developmental Projects &amp; Focus Group documents</td>
<td>35,000</td>
<td>1</td>
<td>90/60</td>
</tr>
<tr>
<td>Volunteers</td>
<td>Developmental Projects &amp; Focus Group documents</td>
<td>300</td>
<td>1</td>
<td>90/60</td>
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<tr>
<td>Individuals or households, Volunteers, NHANES Participants</td>
<td>24-hour developmental projects</td>
<td>200</td>
<td>1</td>
<td>25</td>
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<tr>
<td>NHANES participants</td>
<td>Developmental Projects</td>
<td>1,000</td>
<td>1</td>
<td>90/60</td>
</tr>
<tr>
<td>Subject Matter Experts</td>
<td>Focus Group / Developmental Project Documents</td>
<td>15</td>
<td>1</td>
<td>1</td>
</tr>
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