



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-21-0950]

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 July 20, 2020 to obtain comments from the public and affected agencies. CDC received two non-substantive comments 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. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. 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

The National Health and Nutrition Examination Survey (NHANES), (OMB Control No. 0920-0950, Exp. 11/30/2021) - 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 the Secretary of Health and Human Services (DHHS), acting through NCHS, to 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 (U.S.). 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 (NCHS), CDC. Due to the Coronavirus (COVID-19) pandemic, NHANES 2019-20 paused data collection operations, making this the first time since 1999 that NHANES did not operate on a continuous basis.

NHANES programs produce descriptive statistics, which measure the health and nutrition status of the general population. With physical examinations, laboratory tests, and interviews, NHANES studies the relationship between diet, nutrition, and health in a representative sample of the U.S. NHANES monitors the prevalence of chronic conditions and risk

factors and produces national reference data on height, weight, and nutrient levels in the blood. Results from the 2021-22 NHANES will be used to assess current health measures in the U.S. population.

The program is making changes to NHANES content and procedures for 2021-22. The proposed changes include modifications to sample design, questionnaires, exam components, laboratory content, outreach materials, changes in select interview and exam modes, and changes to operational procedures. NHANES proposes these changes in response to COVID-19 and to address issues such as low response rates. The program consulted with collaborators, stakeholders, and the NCHS Board of Scientific Counselors (BSC). Due to these changes, largely driven by the pandemic, NHANES 2021-22 may not be comparable with previous or future NHANES cycles.

NCHS collects personally identifiable information (PII). Participant level data items 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 low and respond to changing public health needs, NCHS cycles in and out various components. In 2021-22, NHANES plans to continue electronic consent procedures and implement multi-mode eligibility screening. Our yearly goal for

interview, exam, and post exam components is 5,000 participants. To achieve the goal of 5,000 participants interviewed and examined, we need to screen approximately 7,000 individuals annually, a number lower than the approximately 15,000 screened in previous NHANES because NHANES 2021-22 will not oversample based on race, Hispanic origin, or income. In addition, there will be approximately 600 volunteers as part of a dress rehearsal that takes place in two locations (300 volunteers per location.)

In NHANES 2021-22, the interviews that would historically occur via in-person interviews (i.e., screening, family, and sampled participant) will be conducted primarily over the phone. A significant reduction in interview content will occur in 2021-22 so the length of the interviews is feasible for the designed interview modes with reasonable burden to the respondents. Changes will also be made to focus on retaining questions directly related to the interpretation of examination or lab data collected in the survey and relevant to assess the effect of the pandemic. The program plans to add questions related to COVID-19 to the survey to complement NHANES laboratory measures. The program will drop select questions related to examination and laboratory content cycled out of the survey in 2021-22.

Most sections of the NHANES interviews provide self-reported information for use in combination 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, nutrition program participation, and dietary supplement use.

In 2021-22, NHANES will initiate screening for COVID-19 prior to participants entering the Mobile Examination Center (MEC). Participants will be reminded via text or telephone call not to report for their examination appointment if they have been exposed or have tested positive. When participants arrive for the examination appointment, they will answer questions to determine if they have been potentially exposed, they will have their temperature checked and finally will have a COVID antibody test, prior to being allowed in the MEC.

The NHANES examinations that will remain unchanged include anthropometry (all ages), blood pressure (8+), and liver elastography (40).

The program is modifying select examination components in 2021-22. These changes include dropping the DXA spine and femur scans while continuing DXA whole body scans (ages 8-69), dropping all visual assessment subcomponents of the standing balance examination, and modifying the phlebotomy component.

Examination components cycled out in 2021-22 include: Oral Health, Audiometry and Words-in Noise (4 audiometry questions

are retained in the Household Interview), and Cognitive Functioning assessment. NHANES does not plan to conduct a Blood Pressure Methodology Study.

In previous NHANES cycles, while at the examination center, participants were administered a Day 1 dietary recall interview via in-person interview, and additional interview questions were asked (six and older) both in-person and through Audio Computer-Assisted Self-Interview (ACASI). A second 24-hour dietary recall (all ages) was also scheduled to be conducted by phone 3-10 days later. In NHANES 2021-22, both the Day 1 dietary recall and the second 24-hour dietary recall will be completed as telephone interviews. The interview questions will be completed in the examination center primarily via ACASI.

The biospecimens collected for laboratory testing include urine and blood. Serum, plasma, and urine specimens are stored for future testing, including genetic studies, if the participant consents. Consent to store DNA will continue in NHANES.

In 2021-22, we plan to add the following laboratory tests: Serum Terpenes: α -Pinene, β -Pinene, β -Myrcene, Δ -3-Carene, Limonene, β -Caryophyllene, α -Humulene; Magnesium; HPV, serum; Alpha-1-acid-glycoprotein (AGP); Vitamin D; Vitamin A; Vitamin C; Acrylonitrile; Trans-fatty Acids; Blood butyrylcholinesterase activity, blood butyrylcholinesterase concentration, and red blood cell acetylcholinesterase activity; Enterovirus D68; and COVID-19 serology.

In 2021-22, the following laboratory tests will be modified: Hepatitis D (new testing method, reportable findings); Sex steroid hormone panel (now starting at 3+); Urine VOC metabolites (adding as additional 7); trans, trans-Muconic acid; N-Acetyl-S-phenyl-L-cysteine; N-2-Furoylglycine; 2,5-Furandicarboxylic acid; 5-Hydroxymethyl-2-furancarboxylic acid; 5-Hydroxymethyl-2-furoylglycine; and 5-Hydroxy-N-methyl-2-pyrrolidone.

The laboratory tests cycling out for 2021-22 include: HPV swabs (male and female); HPV oral rinse; Home water sample collection to test for fluoride; Salt home collection for iodine assessment; Chromium/Cobalt; Tuberculosis (TB); and Urine flow rate.

NHANES plans to conduct a dress rehearsal prior to fielding the survey as usual. This will be conducted in two locations, among a sample of approximately 300 volunteers per location (approximately 600 total). The program is taking this step to assure it maintains the consistent quality associated with data collection, given the necessary pause in field operations in 2020. The data collected during dress rehearsal will be used for quality control and training purposes. Dress rehearsal data will not be part of the 2021-22 public release.

NHANES plans to conduct developmental projects during NHANES 2021-22 with a focus on planning for NHANES 2023 and beyond. These may include activities such as tests of new equipment, crossover studies between current and proposed

methods, test of different study modes, settings, or technology, outreach materials, incentive strategies, sample storage and processing, or sample designs.

Burden for individuals varies based on their level of participation. For example, infants and children tend to have shorter interviews and exams than adults because young people may have fewer health conditions or medications to report, certain exams are only conducted on individuals 18 and older, etc. In addition, adults often serve as proxy respondents for young people in their families.

Participation in NHANES is voluntary and confidential. There is no cost to respondents other than their time. CDC requests a three-year approval, with 65,630 annualized hours of burden.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)
Individuals in households	Screenener	8,300	1	10/60
Individuals in households	Household Interview	5,600	1	1
Individuals in households	MEC Interview & Examination	5,600	1	2.5
Individuals in households	Day 1 and Day 2 Telephone Dietary Recall & Dietary Supplements	5,600	1	1.3
Individuals in households	Flexible Consumer Behavior Survey Phone Follow-Up	5,600	1	20/60
Individuals in households	Developmental Projects & Special Studies	3,500	1	3
Individuals in households	24-hour wearable device projects	<u>1,000</u>	<u>1</u>	<u>25</u>

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