

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number respondents	Number of responses per respondent	Average burden per response (in hours)
Applicants or fellows	Fellowship Data Collection Instrument	966	1	30/60
Mentors, supervisors, or employers	Fellowship Data Collection Instrument	193	1	30/60
Alumni	Fellowship Data Collection Instrument	1932	1	30/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-23-0950; Docket No. CDC-2022-0133]

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 the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed revision of the information collection project titled National Health and Nutrition Examination Survey (NHANES). NHANES produces descriptive statistics, which measure the health and nutrition status of the general population.

DATES: CDC must receive written comments on or before January 20, 2023.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2022-0133 by either of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without charge, all relevant comments to www.regulations.gov.

Please note: Submit all Federal comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7570; Email: 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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;

4. 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 submissions of responses; and

5. Assess information collection costs.

Proposed Project

The National Health and Nutrition Examination Survey (NHANES), (OMB Control No. 0920-0950, Exp. 04/30/2023)—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 National Health and Nutrition Examination Survey (NHANES) has been conducted periodically between 1970 and 1994, and continuously since 1999 by the National Center for Health Statistics (NCHS), CDC.

NHANES produces 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 United States. NHANES monitors the prevalence of chronic conditions and risk factors and is used to produce national reference data on height, weight, and nutrient levels in the blood. Results from more recent NHANES can be compared to findings reported from previous surveys to monitor changes in the health of the U.S. population over time.

In this Revision, the program is not considering any substantial changes to NHANES content or procedures. The proposed changes being requested

include modifications previously approved via non-substantive change requests in addition to a request for three years of approval. As in previous years, the base sample will remain at approximately 5,000 interviewed and examined individuals annually. It is possible that the survey may have to adapt its plans in response to the novel Coronavirus Disease (COVID-19) or related concerns.

NCHS collects personally identifiable information (PII). Participant level data items will 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 sponsors data collection components on NHANES. To keep burden down and respond to changing public health research needs, NCHS cycles in and out various components. The 2021-22 NHANES physical examination includes the following components: anthropometry (all ages), liver elastography (ages 12 and older), standing balance (ages 20-69), 24-hour dietary recall via phone (all ages), blood pressure measurement (ages eight and older), and dual X-ray absorptiometry (DXA) (ages 8-69, total body scan). While at the examination center, additional interview questions are asked of participants and a second 24-hour dietary recall (all ages) is scheduled to be conducted by phone 3-10 days later.

The 2021-22 survey is similar to what was fielded in 2019-20. NHANES may conduct developmental projects, with a

focus on planning for NHANES 2024 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. The biospecimens collected for laboratory tests include urine and blood. Serum, plasma and urine specimens are stored for future testing, including genetic research, if the participant consents. Consent to store DNA is continuing in NHANES.

Beginning in 2021, NHANES added the following laboratory tests: Acetylcholinesterase Enzyme Activity in whole blood; an Environmental Toxicant in Washed Red Blood Cells (Hemoglobin Adducts); Environmental Toxicants in serum (seven terpenes); Environmental Toxicants in urine (seven volatile organic compound (VOC) metabolites); Infectious Disease Markers in serum (Enterovirus 68 (EV-D68) and Human Papilloma Virus (HPV) in serum); Nutritional Biomarkers in plasma (Four trans-fatty acids (TFA)); and two Nutritional Biomarkers in serum.

Additionally, at the start of the 2021 survey year, the following Laboratory Tests were modified: Steroid hormones in serum (eleven steroid hormones). Cycling out of NHANES is the Blood Pressure Methodology Study and laboratory tests of Adducts of Hemoglobin (Acrylamide, Glycidamide) and Urine flow rate.

Most sections of the NHANES interviews provide self-reported information to be used 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 and nutrition program participation, dietary supplement use, and weight history/self-image related behavior.

NHANES will continue multi-mode screening and electronic consent procedures. Our yearly goal for interview, exam and post exam components is 5,600 participants. To achieve this goal, we may need to screen up to 8,300 individuals annually. Burden for individuals will vary based on their level of participation. For example, infants and children tend to have shorter interviews and exams than adults. This is because young people may have fewer health conditions or medications to report so their interviews take less time or because certain exams are only conducted on individuals 18 and older. In addition, adults often serve as proxy respondents for young people in their families.

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

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Individuals in households	Screener	8,300	1	10/60	1,383
Individuals in households	Household Interview	5,600	1	1	5,600
Individuals in households	MEC Interview & Examination	5,600	1	2.5	14,000
Individuals in households	Telephone Dietary Recall & Dietary Supplements	5,600	1	1.3	7,280
Individuals in households	Flexible Consumer Behavior Survey Phone Follow-Up	5,600	1	20/60	1,867
Individuals in households	Developmental Projects & Special Studies	3,500	1	3	10,500
Individuals in households	24-hour wearable device projects	1,000	1	25	25,000
Total					65,630

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day-23-0010]

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 “Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS)” 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 March 1, 2022 to obtain comments from the public and affected agencies. CDC received two 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

Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS) (OMB Control No. 0920-0010, Exp. 2/28/2023)—Revision—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Birth defects are associated with substantial morbidity and mortality in the United States. About one in every 33 babies is born with a birth defect. Birth defects contributed to more than one million hospital stays in the U.S. in 2013, resulting in \$22.9 billion in hospital costs. Birth defects are the leading cause of infant mortality and the fifth leading cause of loss of potential years of life before age 65. One in five infant deaths is due to birth defects.

For most birth defects, the causes are not known, making prevention efforts challenging to develop. To date, primary preventive measures are available for only a few birth defects. For example, vaccination programs have reduced the incidence of congenital rubella syndrome, Rh hemolytic disease of the

newborn can be prevented by appropriate medical practice, and genetic counseling can provide parents with information about the increased risk of Down syndrome associated with advanced maternal age. Perhaps most importantly, folic acid intake before and during pregnancy can prevent many cases of fatal or permanently disabling neural tube defects such as anencephaly and spina bifida.

This continued burden justifies reasonable attempts to reduce the prevalence of birth defects. To help reduce birth defects among U.S. babies, in 1996 Congress directed the CDC to establish Centers of Excellence for Birth Defects Research and Prevention. The mandate was formalized with passage of the Birth Defects Prevention Act of 1998. This Act amended Section 317C of the Public Health Service Act (42 U.S.C. 247b-4) and authorized CDC to: (1) collect, analyze, and make available data on birth defects; (2) operate regional centers that will conduct applied epidemiological research for the prevention of birth defects; and (3) provide the public with information on preventing birth defects.

In response to this mandate, the Division of Birth Defects and Infant Disorders (DBDID) obtained OMB clearance for data collection that is carried out by the Centers for Birth Defects Research and Prevention (CBDRP). The CBDRP’s first research effort was the National Birth Defects Prevention Study (NBDPS), which began data collection in 1997 and ended in 2013. The CBDRPs transitioned from NBDPS to the Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS), which began data collection in 2014. One of the main activities for each Center is to conduct BD-STEPS in their state, and the purpose of BD-STEPS is to evaluate factors associated with the occurrence of birth defects and stillbirths, and ultimately to work to prevent major birth defects and stillbirths associated with maternal risk factors.

CDC requests OMB approval for an estimated 4,473 annual burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Mothers (Interview)	Core Computer Assisted Telephone Interview.	3,030	1	55/60