

NHANES plans to conduct a blood pressure methodology study. The study population will be NHANES participants aged 6 and older who agree to come to the Mobile Examination Center (MEC).

The bio-specimens collected for laboratory analytes include urine, blood, vaginal and penile swabs, and household water collection. Serum, plasma and urine specimens are stored for future testing, including genetic research, if the participant consents. NHANES 2017–18 plans to add the following lab tests: Three Phthalates in urine (ages 3+); nine urinary flame retardants in urine (ages 3+); one insect repellent in urine (ages 3+); one volatile organic compound (VOC) metabolite in urine (ages 3+); eighteen tobacco biomarkers in urine (ages 3+); two metals in urine (ages 3+); vitamin C in serum (ages 6+); vitamins A, E, and carotenoids in serum (ages 6+); Unsaturated Iron Binding Capacity (UIBC)/Total Iron Binding Capacity (TIBC) in serum (ages 12+); congenital cytomegalovirus (CMV) in sera (ages 1–5); and a test in urine for Mycoplasma genitalium (ages 14–59).

In addition metals in whole blood are changing from a one-half sample to a full sample (ages 1+). Polycyclic

Aromatic Hydrocarbons (PAHs) are being discontinued in the smoker oversample subgroup, however testing will continue in a 1/3 subsample of general NHANES participants.

The 2017–18 survey will also bring back the Flexible Consumer Behavior Survey Phone follow-Up questionnaire for participant ages 1+. This takes place in the home after the second dietary recall is completed.

The following major examination or laboratory items, that had been included in the 2015–2016 NHANES, were cycled out for NHANES 2017–2018: Pubertal maturation, Oral Glucose Tolerance Test (OGTT), oral Human Papilloma Virus (HPV) rinse, Sagittal Abdominal Diameter (SAD), dental fluorosis assessment, dental fluorosis imaging (DFI), plasma, urine and water fluoride, Apo B analysis, three metals in serum and three hormones and binding proteins.

Most sections of the NHANES interviews provide self-reported information to be used either in concert 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.

In 2017–2018, we also plan to implement electronic consent procedures in NHANES. The consent for birth certificate linkage that had been included in previous NHANES will be dropped from NHANES 2017–2018. The survey may conduct a Vaccination Providers' Records Check project with an emphasis on Human Papilloma Virus (HPV), an Ambulatory Blood Pressure Methodology (ABPM) study, test questions related to Chronic Kidney Disease (CKD), adopt digital imaging technology to enhance the existing collection of dietary supplement information, implement multi-mode screening, conduct specimen collection for liver-related DNA markers, and cycle back in consent to store DNA, if resources permit, in the current or in a future cycle of NHANES.

There is no cost to respondents other than their time. Total burden hours requested is 79,894.

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 hours
Individuals in households	NHANES Questionnaire	14,410	1	2.5	36,025
Individuals in households	Blood Pressure Methodology Study Phase 1.	1,404	1	30/60	702
Individuals in households	Blood Pressure Methodology Study Phase 2.	2000	1	30/60	1000
Individuals in households	Flexible Consumer Behavior Survey Phone Follow-Up.	5,000	1	20/60	1,667
Individuals in households	Developmental Projects & Special Studies	3,500	1	3	10,500
Individuals in households	Wearable Device Projects	1,200	1	25	30,000

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–17–16BBS]

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. Written comments and/or suggestions regarding the items contained in this notice should be directed 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

Airline and Traveler Information Collection: Domestic Manifests and the Passenger Locator Form—Existing Information Collection in use without an OMB Control Number—National Center for Emerging Zoonotic and Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Stopping a communicable disease outbreak—whether it is naturally occurring or intentionally caused—requires the use of the most rapid and effective public health tools available.

Basic public health practices, such as collaborating with airlines in the identification and notification of potentially exposed contacts, are critical tools in the fight against the introduction, transmission, and spread of communicable diseases in the United States.

The collection of timely, accurate, and complete contact information enables Quarantine Public Health Officers in CDC's Division of Global Migration and Quarantine (DGMQ) to notify state and local health departments in order for them to make contact with individuals who may have been exposed to a contagious person during travel and identify appropriate next steps.

Under the Public Health Service Act (42 United States Code 264) and under 42 Code of Federal Regulations (CFR) 70.2 CDC can order airlines traveling between states to submit a data set, including airline flight details, and passenger and crew member information, if CDC reasonably believes that a traveler exposed to or infected with a communicable disease of public health concern could have put other passengers at risk for a communicable disease.

In order to collect this data set, aka a manifest, CDC seeking approval for domestic airline and traveler information orders under current authorities in 42 Code of Federal Regulations (CFR) 70.2. This activity is already current practice.

Additionally, CDC requests to transition the Passenger Locator Form (PLF), previously included and approved by OMB in 0920-0134 Foreign Quarantine Regulations, into this

Information Collection Request. Further, CDC is requesting approval for the use of the PLF for the collection of traveler information from individuals on domestic flights. The PLF, a form developed by the International Civil Aviation Organization (ICAO) in concert with its international member states and other aviation organizations, is used when there is a confirmation or strong suspicion that an individual(s) aboard a flight is infected with or exposed to a communicable disease that is a threat to co-travelers, and CDC is made aware of the individual(s) prior to arrival in the United States. This prior awareness can provide CDC with an opportunity to collect traveler contact information directly from the traveler prior to departure from the arrival airport. CDC conducts this information collection under its regulations at 42 CFR 70.6 for domestic flights and 71.32 and 71.33 for flights arriving from foreign countries.

CDC seeks a three-year OMB clearance for this information collection request.

Estimated Annualized Burden Hours

CDC estimates that for each set of airline and traveler information ordered, airlines require approximately six hours to review the order, search their records, and send those records to CDC. CDC anticipates that travelers will need approximately five minutes to complete the PLF. There is no cost to respondents other than their time to perform these actions. For manifest information, CDC does not have a specified format for these submissions, only that it is one acceptable to both CDC and the respondent.

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Airline Medical Officer or Equivalent/Computer and Information Systems Manager.	Domestic TB Manifest Template	1	1	360/60
Airline Medical Officer or Equivalent/Computer and Information Systems Manager.	Domestic Non-TB Manifest Template	28	1	360/60
Traveler	Public Health Passenger Locator Form: Outbreak of public health significance (international flights).	2,700,000	1	5/60
Traveler	Public Health Passenger Locator Form: Limited onboard exposure (international flights).	800	1	5/60
Traveler	Public Health Passenger Locator Form (domestic flights).	800	1	5/60
Total

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-17-0612]

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. Written comments and/or suggestions regarding the items contained in this notice should be directed 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

Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) Reporting System (OMB #0920-0612, exp. 12/31/2016)—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The WISEWOMAN program (Well-Integrated Screening and Evaluation for Women Across the Nation), sponsored by the Centers for Disease Control and Prevention (CDC), was established to examine ways to improve the delivery of services for women who have limited access to health care and elevated risk factors for cardiovascular disease (CVD). The program focuses on reducing CVD risk factors and provides screening services for selected risk factors such as elevated blood cholesterol, hypertension, and abnormal blood glucose levels. The program also provides women with referrals to lifestyle programs and medical care. The WISEWOMAN program provides services to women who are jointly enrolled in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), also administered by CDC.

The WISEWOMAN program is administered by state health departments and tribal programs. In 2013, new cooperative agreements were awarded under Funding Opportunity Announcement DP13-1302. These awards are currently in the final year of funding, but may be extended by CDC

for one additional year, subject to the availability of funds.

CDC collects two types of information from WISEWOMAN awardees. The hardcopy Annual Progress Report provides a narrative summary of each awardee's objectives and the activities undertaken to meet program goals. The estimated burden per response is 16 hours.

In addition, each WISEWOMAN awardee submits an electronic data file to CDC twice per year. The Minimum Data Elements (MDE) file contains de-identified, client-level information about the cardiovascular disease risk factors of women served by the program, and the number and type of lifestyle program sessions they attend. The estimated burden per response for the MDE file is 24 hours.

CDC seeks a one-year extension to enable reporting for the final year of activities funded under the current cooperative agreement and the option year, subject to the availability of funds. There are no changes to the information collected, the burden per response, reporting frequency, the number of awardees, or the total annualized burden hours.

CDC will continue to use the information collected from WISEWOMAN awardees to support program monitoring and improvement activities, evaluation, and assessment of program outcomes. The overall program evaluation is designed to demonstrate how WISEWOMAN can obtain more complete health data on vulnerable populations, promote public education about disease incidence, cardiovascular disease risk-factors, health promotion, improve the availability of screening and diagnostic services for under-served women, ensure the quality of services provided to underserved women, and develop strategies for improved interventions. Participation in this information collection is required as a condition of cooperative agreement funding. There are no costs to respondents other than their time.

The total annualized burden hours are 1,344.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
WISEWOMAN Awardees	Screening and Assessment and Lifestyle Program MDEs.	21	2	24
	Annual Progress Report	21	1	16