Supporting Statement A for Request for Clearance

Developmental Projects to Improve the National Health and Nutrition Examination Survey And Similar Programs

OMB No. 0920-1208
Expiration Date: 05/31/2026

Dual Energy X-ray Absorptiometry (DXA) and Hematology Analyzer and Blood Collection Tube Crossover Studies

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This proposal is a Generic Information Collection request (GenIC) made under the previously approved OMB clearance for Developmental Projects to Improve the National Health and Nutrition Examination Survey and Similar Programs (OMB No. 0920-1208, Exp. Date 05/31/2026), conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). The currently approved generic clearance includes a proposal to conduct developmental studies to "explore, test and evaluate proposed survey designs, content, methods and alternative approaches to activities such as outreach, screening, participant recruitment/retention, data collection, or other health survey activities for National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0950, Exp. Date 04/30/2025) or NCHS wide projects." This submission includes a request to initiate two such studies. The proposed request would not change the currently approved burden hours.

Proposed Study:

Dual Energy X-ray Absorptiometry (DXA) and Hematology Analyzer and Blood Collection Tube Crossover Studies

A. Justification

1. Circumstances Making the Collection of Information Necessary

The National Health and Nutrition Examination Survey (NHANES) is conducted annually and consists of three primary methods of data collection: home interviews, examinations conducted in the Mobile Examination Center (MEC), and laboratory assessments. A major advantage of continuous NHANES data collection is the ability to address emerging public health issues and provide objective data on more health conditions and issues by changing/modifying survey content. Though collected annually, NHANES data are released in two-year cycles. Some survey content stays the same across multiple cycles of NHANES. However, new survey content and health assessments/exams may be added, and existing content and assessments/exams may be modified or dropped at the beginning of each two-year survey cycle.

Testing new methodologies/strategies/projects before they are implemented in the main survey allows NHANES staff to determine how long the protocol will take and how well received the procedure will be among our participants. The results of such testing allow the NHANES program to make changes or adjustments to improve the methodology without affecting the results from the main study. Testing also allows us to compare newer data collection methodologies to previously used methodologies, such that the data can be trended across time. Finally, testing provides hands-on training opportunities for NHANES survey staff responsible for collecting the data and serves as a vital step in making sure NHANES is effective and efficient in its use of resources. Such measures promote improved data quality once the data is collected in the actual survey. This GenIC captures two developmental studies involving volunteers, the burden hours for which have already been approved on line 2 (Developmental Projects & Focus Group documents) of the burden table within the current generic clearance (OMB No. 0920-1208, Exp. Date 05/31/2026).

2. Purpose and Use of the Information Collection

The Division of Health and Nutrition Examination Surveys (DHNES) would like to conduct crossover studies with human subjects to assess the impact of using two new machines within the 2025 NHANES MECs. NHANES seeks to use a new Dual Energy X-ray Absorptiometry (DXA) densitometer system and a new Hematology Analyzer. This generic information collection request details both crossovers individually; however, both studies will be conducted concurrently with the same volunteers.

I. Dual Energy X-ray Absorptiometry (DXA) Crossover Study

DXA was included for the first time in NHANES during NHANES III, 1988-94. Femoral bone mineral density was assessed at that time using pencil-beam bone densitometers (Hologic QDR 1000) in the MECs. In 1999, the DXA component included whole body scans using Hologic QDR 4500A fan-beam bone densitometers; and, in 2005, proximal femur (hip) and anterior/posterior (AP) lumbar spine scans were added to the survey. The current bone densitometers, Hologic Horizon model A (Hologic, Inc.), were purchased in 2018. There are three Hologic Horizon model A systems previously used for DXA examination, with one in each of the three NHANES MECs used during the August 2021-August 2023 cycle. For the 2025-2026 cycle, we will use five new Hologic Horizon model A densitometers, with one in each of the five newly designed MECs.

The information obtained by the scans provide nationally representative data on the following:

1) Total and regional bone mineral content, lean mass, fat mass, and percentage of fat overall and for age, gender, and race and ethnicity;
2) Obesity, defined as an excess of body fat; and
3) Prevalence of osteoporosis and low bone mass.

The information obtained also allow for the study of the association between body composition and other health conditions and risk factors, such as cardiovascular disease, diabetes, hypertension, physical activity, and dietary patterns.

The NHANES DXA data are used to examine age, sex, and racial differences in body composition (bone mineral, lean soft tissue, and fat mass) during the life cycle and to explore the relationship between body composition and behavioral factors, such as diet and physical activity, and physiologic factors, such as diabetes and cardiovascular disease. Bone measurements from DXA enhance the evaluation of skeletal health in the U.S. population by providing estimates of osteoporosis and nationally representative data on bone mineral density (BMD) for participants ages 45 years and older. Femur BMD and questionnaire information on fracture history are used in a risk assessment model to assess absolute fracture risk.

The purpose of the proposed DXA crossover study with participants is:

1) To compare results of participants' scans between the new and the previous systems to calibrate the new DXA densitometer system; and
2) To develop a conversion equation for future scan analysis.

In this proposed crossover study, RTI International (i.e., DHNES' contractor) will lead the recruitment efforts of a convenience sample of 30 volunteers. Three men and three women will be recruited from each of the following age groups: 20-29, 30-39, 40-49, 50-59, and 60-70 years. Ten of the volunteers (one man and one woman in each age category) recruited will have a body mass index greater than 32 kg/m2. DHNES will not be using NCHS or RTI International staff as participants for the study. The study is planned to be performed in the Fall of 2024 over the course of one week at the U.S. Department of Agriculture (USDA) campus in Maryland. During this time, the MEC will not be actively collecting data for NHANES as DHNES prepares for the start of the 2025-2026 NHANES in February of 2025.

Volunteers who meet any of the following criteria are not eligible for the DXA crossover study:

- Females who are pregnant (urine pregnancy testing will be conducted for volunteers, ages 20-59 years);
- A person who has had an X-ray or test with the use of contrast material, such as barium, in the past 7 days;
- A person who weighs over 450 pounds (limitation for examination table);
- A person who is taller than 6'5";
- A person who has a Harrington Rod in the spine for scoliosis; or
- A person who has fractured the hip, had a hip replacement, or has a pin in both hips.
- Non-English speaking
- Any condition for which the MEC physician deems to put the participant at significant risk

Note: Other metal devices, such as pacemakers or dental implants, do not exclude volunteers from the study.

Please see **Attachment 1** for a description of the study and eligibility phone screening questionnaire administered to potential volunteers (Note: Description includes the DXA and hematology crossovers as both studies will be offered to the same volunteers.). Informed consent will be obtained using the attached form (**Attachment 2a**). This form is administered to participants who agree to only participate in the DXA crossover study. Participants who participate in both the DXA and hematology crossovers will provide consent using a separate consent form (**Attachment 2c**).

The DXA images will be transferred from the Hologic computer in the MEC to an RTI laptop via an encrypted USB drive (note: The Hologic computer is standalone and not connected to the internet.). The images are saved on the RTI laptop in a secured environment for analysis by collaborators at the University of Hawaii (UH). The original images will be deleted from the Hologic computer in the MEC. UH collaborators will only access and analyze the images via RTI laptop and will no longer have access to the images once correction factors are calculated. Additionally, after the correction factor calculations are completed, the original and analyzed scans will only be saved on the NCHS server, indefinitely, in case there is a need for future calculations.

The total radiation dose for all the scans planned as part of this protocol is less than 60 µSV, which is considered low and within the range of background radiation. The average effective dose to an individual in the U.S. from background radiation is approximately 3600 µSv per year.

A standard diagnostic x-ray of the spine, for example, delivers an effective radiation dose of 1100 µSv.

A crossover study with participants' data from the new and previous DXA systems will allow NHANES to develop a conversion equation to adjust future scan analysis to monitor trends in osteoporosis and body composition in the U.S. population. Additionally, comparing data from the new NHANES MEC densitometer system with data from the previous system will help assure that future measured changes in national osteoporosis prevalence and body composition will be due to population changes and not due to changes in scan acquisition hardware and software.

II. Hematology Analyzer and Blood Collection Tube Comparison Study (Part 1 & Part 2)

The utilization of NHANES blood data remains a cornerstone of the program, facilitating pivotal contributions to public policy and health. Noteworthy achievements, such as the collection and analysis of blood lead data, have been important in informing corrective adjustments to public health guidelines or recommendations. The ongoing collection of blood from NHANES participants and the enhancement of NHANES laboratory practices are crucial for the continuous monitoring of national public health.

DHNES requests approval to also conduct a two-part hematology comparison study with volunteer human subjects. The first part of the comparison study is to assess the impact of using a new and smaller Beckman Coulter Hematology Analyzer (DxH560) with an improved quality assurance application in lieu of the Beckman Coulter Hematology Analyzer (DxH800), which was used for NHANES data collection through 2023. Hematology analyzers are used to run complete blood counts (CBCs) in NHANES. The second part of the hematology study is to assess the impact of using Serum Separator Tubes (SSTs) in lieu of Red Top Tubes for blood sample collection. The implementation of SSTs could help to speed up sample processing and improve both sample and data quality.

Part 1: Hematology Analyzer Comparison Study

A CBC is a routine blood test used to evaluate overall health and detect a wide range of disorders, including anemia, infection, and leukemia. This comprehensive profile includes a measure of red blood cells (RBCs), including measure of hemoglobin and RBC volume, white blood cells (WBCs), and platelets. A CBC was included for the first time in NHANES I, which was conducted from 1971-1974. In NHANES I, a basic blood draw and analysis in the form of a manual peripheral blood slide that included WBC differential and platelet estimate were included. In NHANES II, conducted from 1976-1980, the blood test included determinations of hemoglobin, hematocrit, red blood cell count, white blood cell count, and differential WBC analysis (to provide a percentage of each type of white blood cell in the blood), red blood cell morphology, and hemoglobin phenotyping performed on a Coulter Model FN. The RBC indices (MCV, MCH, MCHC) were calculated using manually spun microhematocrit value using formulas. RBC indices measure the size, shape, and quality of RBCs.

The information obtained by the CBC provides nationally representative data that will be able to:

1. Estimate anemia from deficiencies and toxicities of specific nutrients in the population and subgroups;
2. Provide population reference data on measures of RBCs, RBC indices, platelets, WBC, and five-part differential;
3. Estimate the contribution of diet, supplements, and other factors to whole blood levels of nutrients; and
4. Further define nutrient requirements as well as optimal levels for disease prevention and health promotion.

NHANES used the Beckman Coulter Hematology Analyzer (DxH800) to measure a participant's CBC through the completion of data collection in 2023. Three DxH800s (Beckman Coulter) were purchased in 2012 and have exceeded their expected lifespan. Beckman Coulter has since upgraded their technology to newer models with streamlined quality assurance application and smaller footprints. Six DxH560s will be purchased to continue reliable hematology testing in NHANES 2025 and beyond while still providing high-quality CBC results. The increase from three units to six units is because we have increased the number MECs in the field at any one time. The DxH560 specifically has enhanced capabilities to:

1. Provide reliable, reportable WBC differential results on the first run through a combination of newer technology;
2. Assess anemia with improved accuracy through enhanced RBC characterization;
3. Improved abnormal results flagging and identification of interferences; and
4. Improved concentrated reagents that can reduce laboratory waste.

This comparison study will be conducted by recruiting 40 volunteers age 20 and older and performing a venipuncture to obtain two Ethylenediaminetetraacetic acid (EDTA) lavender blood tubes of 4ml each. Volunteers' blood will be analyzed on both the new (DxH560) and the current Coulter (DxH800) systems simultaneously. Once all the data are collected, the results will be analyzed by the DHNES Method Validation Team to determine if the results are comparable or are statistically different. The Clinical Laboratory Improvement Amendments (CLIA) certified testing laboratory will be instructed to destroy all samples and sign a destruction form 30 days after the DHNES Method Validation Team completes their analysis. Monthly meetings are held to discuss analysis with statisticians, NHANES lead, and laboratory team. This is routinely done with any change regarding method or instrument change.

Part 1 study purpose

1) To compare the CBC results when run on the new DxH560 and the current DxH800 hematology analyzer to determine if there is a difference in the results. Calibrate the new DxH560; and
2) If there is a statistical difference noted, a regression equation would be created and published in the laboratory documentation file for researchers and their ability to trend the data with confidence knowing that any differences in the results can be attributed to a true population change and not due to changes in new DxH560 hematology analyzer.

Part 2: Blood Collection Tube Type Comparison Study

With the various laboratory analytical methods also comes multiple blood processing and sample type requirements. Whole blood comprises both the liquid component (plasma and serum) and the cellular elements (red blood cells, white blood cells, and platelets) and is used for various tests, including complete blood counts. Serum is the liquid portion of clotted blood, obtained by allowing whole blood to clot and then separating the serum, which can be used for detecting various antibodies, hormones, and metabolites. Typically, serum is obtained from whole blood using either the Red Top Tubes or the SSTs. SSTs contain a clot activator and polymer gel that, when centrifuged, forms a barrier between the serum and the blood cells, facilitating easy and more efficient separation. This innovation revolutionized diagnostic testing by providing a more effective and accurate means of collecting serum for a wide range of laboratory analyses.
As NHANES moves forward with the 2025 redesign, several aspects of laboratory processing have also been redesigned. The implementation of SSTs could help to speed up sample processing and improve both sample and data quality.

Part 2 study purpose
To directly compare results of the biochemistry panel, C-Reactive Protein (CRP), insulin, and Per- and polyfluoroalkyl (PFAS) tests of volunteer participants between Red Top Tubes (old) and SSTs (new) to verify data consistency between collection tube types on current NHANES methods. This study will inform DHNES if SSTs are a feasible option to reduce processing time and maintain sample quality. For example, the study will inform us if the lab test results are comparable between the Red Top and SST serum and no statistical differences are noted.

As previously mentioned, a convenience sample of 40 volunteers will be recruited for this proposed hematology comparison study. The study, which includes these two sub-studies, is planned to be performed in one week, in conjunction with the DXA crossover study, on the U.S. Department of Agriculture (USDA) campus in Maryland where inactive MECs are located. During this study, the MEC will not be actively collecting NHANES data. However, the lab will be open, and consenting volunteers will come at their scheduled appointment time during working hours to have a blood draw. Volunteers will have the equivalent of approximately 1.8 tablespoons of blood drawn. The MEC will be staffed with two Medical Laboratory Scientist (MLS) within DHNES to perform the venipuncture. A DHNES physician will also be present during the study.

Volunteers who meet any of the following criteria are not eligible for either the CBC component or tube study:

- Hemophilia; and
- Cancer chemotherapy within last 4 weeks
- Non-English speaking
- Any condition for which the MEC physician deems to put the participant at significant risk.

Informed consent will be obtained using the attached form (**Attachment 2b**). This consent form is administered to participants who agree to only participate in the hematology crossover study. Participants who agree to participate in both the DXA and hematology crossovers will provide

consent using a separate form (**Attachment 2c**). Similar to the DXA crossover study, recruiting will be based on gender and age. Please see **Attachment 1** for a description of the hematology study and eligibility phone screening questionnaire administered to potential volunteers (Note: Description includes the DXA and Hematology Analyzer and Blood Tube crossovers as both studies will be offered to the same volunteers.). As described in Part 1, samples will be destroyed by the CLIA certified testing lab 30 days after the data has been analyzed by the DHNES Method Validation Team.

The following are known risks associate with venipuncture:

- Hematoma (bruising);
- Swelling, tenderness, and inflammation at the venipuncture site;
- Persistent bleeding; and
- Vasovagal response: fainting, dizziness, sweating, coldness of skin, numbness and tingling of hands and feet, nausea, vomiting, possible visual disturbance, and or fall from fainting.

The information gained from Part 1 of the hematology study will confirm the utility of a new and smaller analyzer that is ideal for data quality and NHANES MEC operations. Results from Part 2 of this study will inform DHNES on the reliability and reproducibility of NHANES lab test results from different source tubes. The change to SSTs will potentially help to increase efficiency of sample processing in the MEC while maintaining the highest data quality.

3. Use of Improved Information Technology and Burden Reduction

The majority of NHANES data are collected from respondents electronically. NHANES uses survey information technology architecture (SITA) that supports fully automated and integrated information technology. SITA provides increased capabilities that allow processing of complex data with significantly less editing than in previous NHANES surveys.

SITA provides NHANES with access to all data that are collected, much of which is available in real-time. The nature of the survey requires that data be accessible at multiple sites including contractor facilities, MECs, field offices, laboratories, and NCHS headquarters. SITA supports: 1) survey planning and design, 2) data collection, 3) data receipt, control and quality assurance, 4) reporting of survey results to survey participants, 5) data review, editing and analysis, 6) generation and documentation of public use data products, 7) tracking of survey respondents; and 8) generation of status reports on all aspects of the survey.

4. Efforts to Identify Duplication and Use of Similar Information

NHANES is a unique source of health information on the U.S. population. Each year, health interview and examination data are obtained. There are no other studies that collect the detailed health, dietary, laboratory and examination data that NHANES does. Duplication of effort is avoided through contacts and discussions with numerous Federal Government agencies during the content development and planning stage of NHANES.

5. Impact on Small Businesses or Other Small Entities

No small businesses are affected. Only individuals will be asked to participate.

6. Consequences of Collecting the Information Less Frequently

   The continuous nature of the NHANES is necessary for several reasons. First, many of the data items collected in the NHANES are used for annual tracking of health events and circumstances, including tracking of the National Objectives for Health Promotion and Disease Prevention. Second, the continuous design makes it possible to aggregate data over longer periods of time to include enough cases to study rare events and small populations. Third, nutrition monitoring legislation explicitly calls for continuous coverage to monitor nutrition changes as they occur. Fourth, a continuous survey is more cost effective because it makes possible a stable field staff, which increases the quality of the data and avoids start-up and shut-down costs. Reducing the frequency of data collection would undermine all of these desirable features of the NHANES.

7. Specific Circumstances Relating to the Guidelines of 5 CFR 1320.5

   This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   a. Federal Register Notice

   The 60-day notice was published in the *Federal Register* on October 21, 2022, Vol. 87, No. 203, page 64049. No additional public comments are required for this GenIC.

   b. Outside Consultation

   The content of NHANES is developed with input from numerous DHHS agencies (including NIH, FDA, and CDC), several USDA entities (Agricultural Research Service (ARS), Economic Research Service (ERS), and Food and Nutrition Service (FNS)), other Federal agencies, non-government organizations, and individuals. The DHHS Data Council has been kept informed of the future NHANES plans. Additionally, NCHS's Board of Scientific Counselors has been informed of future planning.

   NHANES is a collaborative undertaking. Broad input is sought from data users and interested parties to maximize the utility of the survey data. Extensive consultations occur in meetings with NHANES collaborators and interested agencies. A formal research proposal solicitation process occurs prior to content planning and development.

9. Explanation of any payment or gift to respondents.

   Each participant in the DXA study will receive a $100 gift card for their participation. Remuneration in the amount of $30 will also be given, via gift card, to each person who participates in the hematology study. Participants who complete both crossover studies will receive remuneration in the total amount of $130.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

Data will be kept private to the extent allowed by law.

The NCHS Privacy Act Coordinator and the NCHS Confidentiality Officer have reviewed this package and have determined that the Privacy Act is applicable. This study is covered under Privacy Act System of Records Notice 09-20-0164 ("Health and Demographic Surveys Conducted in Probability Samples of the U.S. Population").

The Privacy Act of 1974 (5 U.S.C. 552a) "requires the safeguarding of individuals", and Section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)) requires the safeguarding of both individuals and establishments against invasion of privacy. Contractors who collect information identifying individuals and/or establishments must stipulate the appropriate safeguards to be taken regarding such information. The Privacy Act also provides for the confidential treatment of records of individuals, which are maintained by a federal agency according to either individual's name or some other identifier. This law also requires that such records in NCHS be protected from "uses other than those purposes for which they were collected."

The confidentiality of individuals participating in the GenICs under the Developmental Studies to Improve the National Health and Nutrition Examination Survey and Similar Programs generic package are protected by section 308(d) of the Public Health Service Act (42 USC 242m(d)), which states:

"No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section 304, 306, or 307 may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and in the case of information obtained in the course of health statistical or epidemiological activities under section 304 or 306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form."

In addition, legislation covering confidentiality is provided according to the Confidential Information Protection and Statistical Efficiency Act or CIPSEA (44 U.S.C. 3561-3583) which states:

"(f) Fines and Penalties. -- Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by this section, comes into possession of such information by reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this title, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than 5 years, or fined not more than $250,000, or both."

NCHS also makes the following Confidentiality Pledge:

Assurance of confidentiality (shown on all survey forms) – We take your privacy very seriously. All information that relates to or describes identifiable characteristics of individuals, a practice, or an establishment will be used only for statistical purposes. NCHS staff, contractors, and agents will not disclose or release responses in identifiable form without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act or CIPSEA (44 U.S.C. 3561- 3583). In accordance with CIPSEA, every NCHS employee, contractor, and agent has taken an oath and is subject to a jail term of up to five years, a fine of up to $250,000, or both if he or she willfully discloses ANY identifiable information about you. In addition to the above cited laws, NCHS complies with the Federal Cybersecurity Enhancement Act of 2015 (6 U.S.C. §§ 151 and 151 note), which protects Federal information systems from cybersecurity risks by screening their networks.

All study data will be collected under the pledge of confidentiality. Consequently, all information collected in Developmental Studies to Improve the National Health and Nutrition Examination Survey and Similar Programs will be kept confidential, with an exception for suspected child abuse. When indicated, studies will collect, on a confidential basis, data needed to re-contact respondents for additional information and for participation in potential follow-back surveys, and possibly to match respondents to administrative records. The ability to track respondents and match to other records greatly expands the usefulness of these data at very low cost.

Only those NCHS employees, contract staff, and full research partners who must use the personal information for a specific purpose can access and use such data resulted from the studies. Everyone else who uses the data can do so only after all identifiable information is removed.

As described in section 2 of this information collection request, the DXA scans will be deleted from the Hologic computer in the MEC, and collaborators will only access and analyze the images via RTI laptop in a secured environment. Once correction factors are calculated, collaborators will no longer have access. The original and analyzed scans will be saved on the NCHS server indefinitely. For Part 1 and Part 2 of the hematology study, the CLIA certified testing lab will be instructed to destroy all samples and sign a destruction form 30 days after the DHNES Method Validation Team completes their analysis.

For more than 50 years, NCHS has protected confidential information collected in its surveys. The collection of identifiable information requires strong measures to ensure that private information is not disclosed accidentally or deliberately in a breach of confidentiality. All NCHS employees, as well as all contract staff, receive appropriate confidentiality training and sign a "Nondisclosure Statement." Staff members of collaborating agencies are also required to sign this statement, and outside agencies are required to enter into a more formal agreement with NCHS. All contractor and NCHS project staff follow strict procedures to collect, monitor, and analyze these data. This procedure prevents information from being removed from the area for purposes other than official NCHS survey data collection. The transmission and storage of

confidential data are protected through procedures such as encryption and carefully restricted access. Only those NCHS employees and our full research partners who must use the personal information for a specific purpose may have access to and use such data.

11. Ethics Review Board (ERB) and Justification for Sensitive Questions

The National Health and Nutrition Examination Survey is subject to review by NCHS' Research Ethics Review Board (ERB). The NCHS Human Subjects Coordinator determined that NHANES DXA and Hematology Crossover studies is a public health surveillance activity under the 2018 requirements of the Common Rule (45 CFR 46.102(I)(2)). On October 17th, 2024, the NCHS ERB determined that NHANES DXA and Hematology Crossover studies is approved (see **Attachment 4**). The voluntary crossover studies do not include sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

a. Time Estimates

The time allotment for the DXA crossover study is approximately 40 minutes. To perform the DXA crossover on the two DXA machines (new machine and old machine) it will take approximately 20 minutes on each machine. The 20 minutes includes: time for the introduction, pre-exam questions, positioning and the whole-body scan (3 minutes each), and the femur and spine scans (1 minutes each). When all scans have been completed, the finding will be reviewed with the participant for an additional 5 minutes. The maximum number of respondents will be 30 volunteers ages 20-70 years. The maximum burden is 23 hours (30 respondents*45/60 hours = 23 hours).

The time allotment for venipuncture in the hematology crossover study is approximately 10 minutes. The maximum number of respondents will be 40 volunteers age 20 years and older. The maximum burden is 7 hours (40 respondents*10/60 hours = 7 hours).

The total burden hours for the DXA and hematology crossover studies, 30 hours, were already budgeted and approved in line 2 ("Developmental Projects & Focus Group documents") of the Developmental Projects to Improve the National Health and Nutrition Examination Survey and Similar Programs (OMB No. 0920-1208, Exp. Date 05/31/26). No additional burden is sought.

TABLE 1 – ANNUALIZED BURDEN HOURS AND COSTS

Type of Respondent	Form	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Volunteers, ages 20-70	DXA crossover study	30	1	45/60	23

Volunteers, age 20 and older	Hematology comparison study	40	1	10/60	7
Total					30

b. Annualized Cost to Respondents

The hourly wage rate of $31.48 is based on the latest income estimates (i.e., from May 2023) released on 04/03/24 from the Bureau of Labor Statistics: Occupational Employment and Wages - May 2023 (bls.gov) (last accessed 9/12/24). This wage rate for the category "all occupations" was used since respondents do not fall into a single economic or occupational category (Note: There are no costs for participants. They may receive remuneration as a token of appreciation and to help with out-of-pocket expenses such as babysitting/childcare and transportation, when appropriate.).

TABLE 2 – ANNUALIZED COST TO RESPONDENTS

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Volunteers, ages 20-70	DXA crossover study	23	$31.48	$724
Volunteers, age 20 and older	Hematology comparison study	7	$31.48	$220
Total				$944

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no additional costs.

14. Annualized Cost to the Federal Government

While actual annualized costs will vary dependent on the scope of future survey submissions, it is anticipated that the costs related to staff salaries for planning and implementing the future surveys might average $100,000.

15. Explanation for Program Changes and Adjustments

This GenIC will use 30 hours.

16. Plans for Tabulation and Publications and Project Time Schedule

DHNES has no plans for publishing any analytic work based on this data collection. Any tabulations will be strictly limited to statistical work to make comparisons as described above. The DXA and hematology studies would be conducted for one week immediately after clearance has been received. The tentative start date is planned for a week in early-December.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submission

The certifications are included in this submission.