

National Health and Nutrition Examination Survey

OMB No. 0920-0950

(Expires November 30, 2021)

**Nonsubstantive Change to conduct
NHANES Developmental Projects**

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This is a request for nonsubstantive changes to the National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0950, Exp. Date 11/30/2021), conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). The currently approved package includes a proposal to conduct developmental studies to support NHANES data collection. Blood collection via heel stick or finger stick on infants less than 12 month old was previously approved but was never initiated. This submission includes a request to initiate an infant blood collection pilot study using venipuncture blood collection. The burden hours for this project have already been accounted for within the Developmental Projects & Special Projects line in the most recently approved revision. Findings from these studies will be reported to OMB and uploaded to Reginfo.gov.

Proposed Pilot Study

- Blood Collection – Infants less than 12 months old – venipuncture, complete blood count and Vitamin D
- Update measurement list to add vitamin D (Attachment 1c)
- Infant health questions added – Safety Exclusion Questionnaire, Follow-up Questionnaire for Venipuncture Refusal (Attachment 1b)

A. Justification

Circumstances Making the Collection of Information Necessary.

NHANES is conducted annually. It includes a household interview, physical measures and additional interviews done in the NHANES Mobile Examination Centers (MECs). There may also be follow-up interviews or components (such as a second dietary interview) that take place after the MEC exam. 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 may be added, existing content may be modified or some content may be dropped at the beginning of each two-year survey cycle.

There is great value in testing new methodologies before they are implemented in the main survey. Testing 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 also allow the NHANES program to make changes or adjustments to improve the methodology without affecting the results from the main study. Finally, it also provides hands on training opportunities for NHANES survey staff responsible for collecting the data. Testing is 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. Since data collection is continuous, methodology studies must be conducted during ongoing NHANES data collection. This nonsubstantive change request captures one such methodological study, the burden hours for which have already been approved on line 6 (Developmental Projects & Special Studies) of the burden table within the current package (OMB No. 0920-0950, Exp. Date 11/30/2021).

1. Purpose and Use of the Information Collection

Currently, NHANES collects and performs analyses on blood from survey participants 1 year of age and older. Thus, no national data from NHANES are currently available on the blood levels of relevant analytes for survey participants younger than 1 year of age. NHANES currently collects data on dietary exposures of infants and new questions were added to NHANES 2019 that will support resulting data from infant blood draws. An infant blood pilot test to conduct a heel stick (0 to 6 months) or a finger stick (6 months to less than 12 months) was approved as a non-substantive information collection on 9/8/2017. Since that time, venipuncture blood collection has been chosen over capillary blood collection (i.e., finger sticks and heel sticks) techniques in this population. Venipuncture is the preferred method of drawing blood from neonates due to the blood volume being collected and venipuncture has been shown to cause less pain than heel-pricks (Shah, et al, 2007). In addition, capillary blood is a combination of both arterial and venous blood, which results in higher hemoglobin and hematocrit values, when compared to venous blood samples (Kayiran, et al., 2003). Lastly, venipuncture was the chosen technique because of quality (i.e., capillary blood sample may include cellular fluid) and volume concerns of the sample as compared to collection of capillary blood. NHANES developed the NHANES Venipuncture Blood Collection Pilot in participants less than 12 months, in collaboration with the U.S. Department of Health and Human Services (HHS) Office of Disease Prevention and Health Promotion (ODPHP). The NHANES Medical Officer of the Planning Branch's project determined that it was best to mimic the venipuncture procedure that NHANES uses for children 1-2 years old, which has been in place for well over 2 decades, rather than continue with the finger/heel stick. This procedure yields the best quality and quantity of blood sample with the least amount of pain.

When drawing blood from infants, smaller volumes of blood must be taken compared to the volumes that can be acquired from older children and adults. New analytic methods have been developed by the Centers for Disease Control and Prevention's National Center for Environmental Health (NCEH) to do a number of analyses on low volumes of blood, greatly enhancing the public health significance of collecting blood from infants in NHANES. The low blood volume analytes include: a complete blood count (CBC), ferritin and transferrin, folate, c-reactive protein and alpha-1-acid glycoprotein, retinol binding protein, vitamin D, heavy metal panel and per- and polyfluoroalkyl substances. The findings will also allow the agencies and Departments supporting this work to evaluate the utility of implementing infant blood draws at full-scale in the regular NHANES. In addition, the proposing collaborators in conjunction with the NHANES laboratory team and NHANES leadership have determined that additional measures (complete blood count and Vitamin D) and three sets of infant health questions should be added to the project. It is therefore necessary to submit a new nonsubstantive information collection request for an infant blood draw pilot, as the desired scope of the project has changed.

The purpose and uses of the study are detailed below. The project will include NHANES participants. Participation is voluntary. Testing would take place across multiple NHANES locations, as needed, to achieve the desired sample size. This study would begin, as soon as feasible, after approval has been received.

Blood Collection – Infants < 1 year old

The relationship of early child nutrition to health outcomes throughout the lifespan has grown as an important public health interest. From birth to 12 months is a critical life stage nutritionally because of the increased demand for nutrients to support growth and development. Early child nutrition impacts taste preferences, dietary behaviors, and the development of dietary patterns. Inadequate intake of nutrients, poor diet behaviors, and unhealthy weight gain in early childhood lead to numerous developmental and long-term health problems. Traditionally, the Dietary Guidelines for Americans (Sec. 4204 of - <https://www.congress.gov/bill/113th-congress/house-bill/2642>) have focused on individuals ages 2 years and older. The Agricultural Act of 2014 has mandated that beginning with the 2020-2025 edition, the Dietary Guidelines include comprehensive dietary recommendations for children from birth to 24 months (0-24 mo.). As a result, nationally representative data on children 0-24 months are crucial to advancing the science base used to inform current and future Federal nutrition and related health programs, policies, and consumer information. Currently, NHANES collects and analyses blood from children 1 year of age and older. Thus, no data are currently available on the blood levels of relevant analytes for infants 0 to less than 12 months. This proposal addresses the opportunity for a pilot study to lay the foundation for moving towards regularly collecting blood from all infants in NHANES.

The proxy (parents /guardians etc.) of up to 100 NHANES participants from birth to less than 12 months, would be asked to consent to their infants' blood being drawn. The amount of time needed for this project is estimated at 15 minutes per participant. The estimated time in the original request was 8 minutes. This time was increased to 15 minutes in this request to allow for time to explain the additional measures (CBC and Vitamin D) and for the added questions about infant health that the parents/guardians will be asked. This pilot will take place at multiple NHANES locations until the necessary sample size is obtained. Select findings will be reported to participants (see attachment 1d).

The objectives of this project can be summarized as follows:

- Obtain blood collection for participants 0 to less than 12 months
- Assess how much blood can be obtained
- Assess/track the rate of participation
- From the blood collection, obtain the following measures
 - Complete Blood Count
 - Metals panel for Lead (Pb)
 - Metals panel for total mercury (for estimating methylmercury, MeHg) folate
 - Ferritin and soluble transferrin receptor (sTfR)
 - C-reactive protein (CRP) and alpha-1-acid glycoprotein (AGP)
 - Retinol Binding Protein (RBP)
 - Per-and polyfluoroalkyl substances (PFASs) panel
 - Vitamin D

This pilot test was proposed by a collaborative effort among the following agencies:

- CNPP Center for Nutrition Policy and Promotion, USDA
- EPA Office of Water, Standards and Health Protection Division,
Environmental Protection Agency

- ERS Economic Research Service, USDA
- FNS Food and Nutrition Service, USDA
- NCBDDD National Center on Birth Defects and Developmental Disabilities, CDC, HHS
- NCCDPHP National Center for Chronic Disease Prevention and Health Promotion, CDC, HHS
- NCI National Cancer Institute, NIH, HHS
- NHLBI National Heart, Lung, and Blood Institute, NIH, HHS
- NICHD National Institute of Child Health and Human Development, NIH, HHS
- ODPHP Office of Disease Prevention and Health Promotion, OASH, HHS
- ODS Office of Dietary Supplements, NIH, HHS

Hemoglobin is included in a complete blood count (CBC) among other tests such as white and red blood cell counts, hematocrit and platelet counts. NHANES mobile examination centers are already equipped with instrumentation to perform a CBC, which we currently perform on participants one year and older. Initiating this pilot will capture the same information on those less than 12 months that is already collected on those 1 year and older. No additional instrumentation will need to be purchased to complete this testing.

A vitamin D assessment was not included in the original clearance request. It is included in this revised request for the following reasons. The American Academy of Pediatrics recommends, beginning at birth, that all infants consume 400 IU of vitamin D per day. Human milk is not a good source of vitamin D; therefore, for infants consuming human milk either as the sole source or a partial source of nutrition, vitamin D supplementation is recommended (Wagner and Greer 2008). For infants who are not consuming enough vitamin D fortified formula (i.e., <1,000 mL/d), vitamin D supplements are recommended. Monitoring if these recommendations are adhered or not is a public health concern. In addition, the updated regulations of the Food and Drug Administration for the Nutrition Facts label requires vitamin D to be listed on food packaging; thus, monitoring vitamin D status is a priority (FDA 81 FR 33741).

Reference: Food Labeling: Revision of the Nutrition and Supplement Facts Labels. 81 FR 33741. Available at: <https://www.regulations.gov/document?D=FDA-2012-N-1210-0875> accessed November 1, 2018.

The NHANES Health Measurements list will be updated to include the tests for this pilot in this age group (see attachment 1c). More details about blood collection in infants less than 12 months old are provided in Attachment 1a and 1b. For an example of the Report of Findings, see attachment 1d.

9. Explanation of any payment or gift to respondents.

Participants in the pilot studies described in this non-substantive clearance request will not receive any additional incentives. They will simply receive the already approved incentives given to regular NHANES participants.

12. Estimates of Annualized Burden Hours and Cost

The Blood Collection – Infants Pilot Study is budgeted for 15 minutes. The maximum number of respondents would be 100 infants. The maximum burden is 25 hours (100 respondents*15/60 hours = 25 hours). This time was already budgeted and approved in line 6 (“Developmental Studies & Special Projects) of the original submission. No additional burden is sought.

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
Blood Collection – Infants Pilot Study Participants	Blood Collection – Infants Pilot Study Form	100	1	15/60	25
Total		100			25

15. Explanation for Program Changes and Adjustments. The project described in this submission does not change the burden hours from the previously approved clearance. The burden hours in this submission are captured in the “Developmental Studies & Special Projects” line of the burden table currently approved for NHANES.

List of attachments:

- 1a. Blood Collection – Infants Description
- 1b. Blood Collection – Infants Form
- 1c. Blood Collection – Infant Measurement List
- 1d. Blood Collection – Report of Findings