National Health and Nutrition Examination Survey
OMB No. 0920-0950
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Nonsubstantive Change to conduct Blood Pressure Cuff Comparability Study and Feasibility of Urine Collection in Children 3-5 Years Old

Contact Information

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This is a request for a nonsubstantive change to the National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0950, exp. November 30, 2013), conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), to conduct pilot/ methodological studies. Burden for this project has already been approved; thus, no change to the burden is requested.

The studies planned include the following:

a) NHANES Urine Collection Feasibility Study in Children Ages 3-5 years
A timed spot urine specimen is routinely collected in the NHANES for participants 6 years and older. There is now interest in expanding the target group to include children 3-5 years old. This study will determine if it is feasible to collect spot urines from children 3-5 years old in NHANES.

b) Blood Pressure Cuff Comparability Study
A Blood Pressure Working Group has recommended that a new blood pressure cuff comparability study be conducted to aid in assessing findings from the NHANES Blood Pressure Methodology Study conducted in 2009-2010

A. Justification

1. Circumstances Making the Collection of Information Necessary.

The National Health and Nutrition Examination Survey (NHANES) contributes to the mission of CDC by collecting objective data that are used to promote health and to prevent and control disease and disability. CDC works with partners throughout the nation and the world to monitor public health, formulate and implement prevention strategies, develop health policies, promote healthy behaviors, and foster safe and healthful environments. In addition to the groups within the CDC, NCHS collaborates with over two dozen federal agencies to plan and fund the NHANES. The survey partners include numerous institutes of the National Institutes of Health, several programs within the U.S. Department of Agriculture, the Food and Drug Administration, and the U.S. Environmental Protection Agency. NHANES data are used to assess environmental exposures; evaluate nutrition program and policy impacts; and estimate prevalences of health risk factors, chronic conditions, and infectious diseases.

NHANES is a continuous survey, meaning survey data are collected every year. It includes a household interview, done in participants' homes and physical measures and additional interviews done at the NHANES Mobile Examination Center (MEC). There may also be follow-up interviews or components (such as a 2nd dietary interview or the physical activity monitor (PAM)) 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. Because of the NHANES sample design, data are released in two year cycles. Some of the survey information gathered may change at the beginning of each two year cycle. In some cases, this means new content will be added. In other cases, this means that existing content may be modified.

New methodology must be tested before being implemented. There are many reasons for this. This allows us to find out how long the procedure being tested will take or 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. 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 an actual survey. Since data collection is continuous, methodology studies must be conducted during ongoing NHANES data collection.

2. Purpose and Use of the Information Collection

The purposes and uses of each study are detailed below. Tests will include NHANES participants or paid volunteers (in circumstances when there aren't enough NHANES participants in the pilot's target group or when the pilot cannot be conducted in the NHANES setting, etc.). Participation is voluntary. Tests will be conducted as soon as clearance is received.

a) NHANES Urine Collection Feasibility Study in Children Ages 3-5 Years

A timed spot urine specimen is routinely collected in the NHANES for participants 6 years and older. There is now interest in expanding the target group to include children 3-5 years old.

This study will determine if it is feasible to collect spot urines from children 3-5 years old in NHANES. The urine will be used for the same purposes as the existing NHANES urine samples. These uses include determining:

- which select chemicals participants, including younger children, are exposed to and at what concentrations
- the prevalence of participants with toxic levels for chemicals with a known toxicity level
- whether chemical exposure levels are higher among subgroups, such as children 3-5 years old, who are potentially more vulnerable due to their young age and youthful behaviors.

The Canadian Health Measures Survey, which is similar to NHANES, has conducted this collection in 3-5 year olds and released its first data from this effort in 2013. http://news.gc.ca/web/article-eng.do?nid=733439

More details about the NHANES Feasibility Study of Urine Collection in 3-5 year olds are provided in Attachment A.

b) Blood Pressure Cuff Comparability Study

Accurate blood pressure measurement depends on a number of factors, including equipment. In 2009-2010, NHANES conducted a Blood Pressure Methodology Study, where one cuff was used with two different blood pressure devices. Previous validation studies used blood pressure devices with their accompanying blood pressure cuffs. Although the general functionality of

blood pressure cuffs is similar across different blood pressure devices, there is no actual data on the compatibility of blood pressure cuffs among different devices.

On July 18th, 2011 a Blood Pressure Workgroup expert panel was assembled and charged by NHLBI to review the results of the 2009-2010 NHANES Blood Pressure Methodology Study. The panel had concerns about the accuracy of the findings since the accompanying Omron cuff was not used with the Omron HEM 907-XL. To address these concerns, the expert panel suggested that a comparability study be undertaken to compare the standard Omron cuff to the standard Baumanometer cuff.

The purpose of this study is to respond to the expert panel's recommendation. To accomplish this goal, the current study being proposed will take blood pressure measurements using the following two scenarios:

- two identical Omron HEM-907 XL machines will be used to take blood pressure, using the standard Omron cuff with each device- three measurements will be taken per device
- two identical Omron HEM-907 XL machines will be used to take blood pressure; however, one Omron machine will be connected to the standard Omron cuff and the other Omron machine will be connected to a Baumanometer cuff- three measurements will be taken per device.

This study will be conducted by NHANES staff using the Johns Hopkins University ProHealth facility located in Baltimore, MD. NHANES has partnered with this organization because they have existing examination space and an existing pool of volunteers to recruit from. While NHANES staff will conduct the study, Johns Hopkins Pro Health staff will do the recruiting and obtain informed consent from participants. Participants will be volunteers who are not part of the regular NHANES sample.

A report of this study's findings will be given to the expert blood pressure panel. The panel will use this information to better evaluate the findings from NHANES Blood Pressure Methodology Study conducted in 2009-2010.

More details about the Blood Pressure Cuff Comparability Study are provided in Attachment B.

9. Explanation of any payment or gift to respondents.

No additional remuneration will be offered for NHANES Feasibility Study of Urine Collection in 3-5 year olds.

Participants in Blood Pressure Cuff Comparability Study will be remunerated $30 for their time. This amount is comparable to remuneration given to paid volunteers in other NHANES pilot tests or special studies. These participants will be volunteers who are not part of the regular NHANES sample.

12. Estimates of Annualized Burden Hours and Cost.

The NHANES Feasibility Study of Urine Collection in 3-5 Year Olds has been budgeted for 5 minutes. We will test at multiple NHANES locations until a sample of 125 participants has been reached. (For example, if 21 participants are successfully recruited per site, this would be completed in 6 NHANES locations.) The maximum number of respondents would be 125 (ages 3-5) and the maximum burden 10 hours (125 respondents *5/60 hour = 10 hours).

The Blood Pressure Cuff Comparability Study has been budgeted for 35 minutes. The maximum number of respondents would be 136 adults and the maximum burden 79 hours (136 respondents*35/60 hour = 79 hours).

The total burden is 89 hours. This time was already budgeted and approved in line 2 (Special Studies) of the original submission. No additional burden is sought.

15. Explanation for Program Changes and Adjustments. There are no changes in this package from the previous-approved clearance. The burden hours were approved by OMB in the full clearance.

List of attachments:

A. NHANES Feasibility Study of Urine Collection in 3-5 Year Olds
B. Blood Pressure Cuff Comparability Study