National Health and Nutrition Examination Survey

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Change to Conduct Dried Blood Spot Methodology Study in NHANES

Contact Information

Vicki L. Burt, ScM RN
Chief, Planning Branch
National Health and Nutrition Examination Survey
National Center for Health Statistics/CDC
3311 Toledo Road, Room 4211
Hyattsville, MD 20782

Telephone: 301-458-4127
FAX: 301-458-4028

E-mail: vburt@cdc.gov

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This is a request for a non-substantive/generic change to the approval of the National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0237, exp. December 31, 2011), conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention, to conduct a methodological study in NHANES. Burden for this project has already been approved; thus, no change to the burden is requested.

The methodological study planned is a study of Dried Blood Spot (DBS) collection methodology on respondents 20 years and older. The study will take place in the NHANES Mobile Examination Center.

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. 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 this methodological study are detailed below. All tests will include only NHANES participants. Participation is voluntary.

The NHANES program routinely assesses new methods for collecting biomedical data in the household and the mobile examination center. New methods ensure that NHANES continues to establish national standards in health measure data collection. Dried Blood Spot (DBS) collection has been used in several studies such as the National Longitudinal Study of Adolescent Health (ADD Health); the Health and Retirement Study (HRS); and the National Social Life, Health, and Aging Project (NSHAP). DBS has several advantages and disadvantages when compared to venous blood collection (noted below). In addition, considering the interest in DBS by other community-based studies and the National Health Interview Study (NHIS), NHANES is the appropriate mechanism to evaluate the comparability of DBS and a venous blood collection.

This methodology study will compare Dried Blood Spot test results to venous blood test results, using DBS and venous blood collected in the mobile examination center (MEC). There are two parts to the study. The first part will consist of collecting DBS from venous blood. The second part will consist of collecting DBS from blood obtained through finger sticks. Our interest is in assessing the ease of DBS collection and the accuracy and reproducibility in the measurement test results.

The protocol for the DBS Methodology Study Mobile Examination Center Component is provided in Attachment A.

9. Explanation of any payment or gift to respondents.

This is an additional “invasive" procedure for survey participants who volunteer for this special study. These participants will have the venipuncture (blood draw using a needle) collected first, then the fingerstick (blood draw using a lancet). While the fingerstick is a very simple and quick procedure, it can cause additional discomfort for the participant. A fingerstick can actually be more acute than a venipuncture, since all the nerve endings on the fingertip, used to feel objects, are located at the site of the fingerstick. Up to two fingersticks may be conducted, if a single fingerstick does not yield sufficient blood. Survey participants 20 years and older, including participants with diabetes (who may already perform fingersticks as part of their diabetes control efforts), will be eligible for this special study. We request a $10 dollar remuneration for participants in this methodological study, in order to show appreciation for their contributions of additional time, blood sample, potential discomfort, and to ensure adequate response rates. This is consistent with procedures for previous NHANES special studies, where additional remuneration was allowed.

12. Estimates of Annualized Burden Hours and Cost.

Burden category	Number of respondents for eight weeks	Number of responses per respondent	Average burden per response (hours)	Total respondent burden (hours)
Follow-up and Special Studies				
MEC Dried Blood Spot	400	1	5/60	33
				33

DBS Methodology Studies

The MEC Dried Blood Spot Methodology study has been budgeted for 5 minutes. We will test for a total of eight weeks, across two NHANES PSUs (four weeks per location, 200 respondents per location). The maximum number of respondents would be 400 (ages 20+) and the maximum burden 33 hours (400 respondents *5/60 hour = 33 hours).

The total burden is 33 hours. This time was already budgeted and approved in line 6. (Follow-up and 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. Protocol for Dried Blood Spot Methodology Study (Mobile Examination Center Component)