

**National Health and Nutrition Examination Survey (Generic Clearance)**

**OMB No. 0920-0237**  
(Expires November 30, 2012)

**GenIC to Conduct the Health Measures at Home Study**

**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](mailto:vburt@cdc.gov)

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This is a request for a Gen IC in the National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0237, exp. November 30, 2012), 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 generic project has already been approved; thus, no change to the burden is requested.

The methodological study planned is the Health Measures at Home Study (HMHS), which will be conducted on respondents 18 years and older. The study will take place both in the NHANES Mobile Examination Center (MEC) and in a respondents' home.

Data collected for this study will be used to evaluate differences between NHANES MEC measurements and home based measurements when controlling for data collector skill level, environment, and equipment. More details about the Health Measures at Home Study (HMHS) are provided in Attachment A.

In each location the following will be collected:

**In the MEC**

- Height
- Weight (2 measurements)
- Blood pressure
- Dried blood spots

**In the home**

Lay Interviewer

- Height
- Weight (2 measurements)
- Blood pressure (1 to 2 measurements)
- Dried blood spots

Health Technician

- Height
- Weight (2 measurements)
- Blood pressure (1 measurement)
- Dried blood spots

A. Justification

1. Circumstances Making the Collection of Information Necessary.

The NHANES program routinely assesses new methods for collecting biomedical data in the household and/or in the MEC. New methods ensure that NHANES continues to establish national standards in health measure data collection. Data from the examination portion of NHANES are used to obtain objective health measures, but the logistics of the survey limits the ability to provide annual and sub-national estimates. Conversely, adding biological measures to a large household survey, such as the National Health Interview Survey (NHIS) (OMB No. 0920-0214, exp. August 31, 2014), could provide detailed sub-national information that would be useful in targeting and assessing intervention programs.

The NHIS collects data on a broad range of health topics through personal household interviews. NHIS provides representative health estimates by geographic, demographic, and socioeconomic subgroups. NHIS does not collect physical examination or biologic specimens. At this time there is no federal mechanism to collect annual sub-national physical examination and biologic specimens. This ability to collect such data has increased importance since the Department of Health and Human Services has launched the Million Hearts Initiative, with the goal of reducing heart attacks and strokes by 1 million over the next five years.

NCHS seeks to investigate the feasibility of incorporating physical measures and biologic specimen collection into the NHIS by implementing the HMHS within NHANES.

## 2. Purpose and Use of the Information Collection

The HMHS will examine a total of approximately 130 respondents. Respondents ages 18 and above are eligible for this study to match exactly the age eligibility of the NHIS. At the MEC, eligible respondents are asked if they would like to participate in HMHS. Informed consent for the HMHS will be documented electronically at the MEC.

NHANES components will have priority over the HMHS to ensure that this special study does not interfere with regular NHANES data collection. Respondents will be invited to participate in the HMHS as time allows. To ensure comparisons can be made to venous blood, dried blood spots (DBS) collection will occur immediately after venipuncture.

### MEC Component

The HMHS will be conducted in two parts. The first part of the study takes place in the MEC with portable equipment suited for in-home use. Respondents will have their height, weight and blood pressure measured and DBS will be collected. This will be done to compare and assess the magnitude of difference between the MEC equipment and the equipment that would be used in a home environment, under the standardized setting that the MEC provides.

DBS will be collected by a trained phlebotomist. Up to two finger sticks will be collected per respondent. The DBS will be analyzed for C-reactive protein (CRP), glyco-hemoglobin (HbA1c), high-density lipoprotein (HDL), and total cholesterol (TC). DBS will be compared to the MEC venous blood specimens.

Respondents will have their weight measured twice to test two models of scales. One scale requires 200 pound weights for calibration and the other is a self-calibrating scale. Using both scales for this project will help to inform the selection of a scale for use on NHIS.

The blood pressure measurement consists of three consecutive inflations with 30 second waiting periods between inflations. The individual burden in the MEC is expected to be about 26 minutes.

After the completion of the MEC examination, an in-home appointment will be scheduled with

the respondent. This will be done to collect the same measurements in the home as were collected in the MEC as part of the HMHS. The blood specimens will be collected through DBS. The physical measurements and DBS will be collected twice. One set of measurements will be collected by a lay interviewer and the second set of measurements will be collected by a trained health technician. Both the interviewer and health technician will perform their data collection during the same visit to the respondent's home.

### Home Component

The in-home physical examination measurements include height, weight, blood pressure and DBS. Height will be measured once by each examiner. Two weight measurements will be obtained by each examiner, using two different scales. Each examiner will take blood pressure measurements. If a respondent who wears a sleeve is unwilling or unable to roll up their sleeve, the blood pressure measurements will be taken over the sleeve and it will be noted that it was taken over clothing. Respondents who roll up their sleeve for the blood pressure measurements will be asked to roll down their sleeve for a third BP reading by the interviewer. Each examiner will perform up to two finger sticks. The number of finger sticks depends on whether the examiner was successful in filling five blood spots. In the home portion of the study, respondents will receive their blood pressure findings.

Data collected for this study will be used to evaluate differences between NHANES MEC measurements and home based measurements when controlling for data collector skill level, environment, and equipment. More details about HMHS are provided in Attachment A.

### 9. Explanation of any payment or gift to respondents.

Participants in HMHS will be given additional remuneration. These participants will have two additional physical examinations in their home, one conducted by a trained interviewer and one conducted by a MEC Technician. DBS will also be collected via finger stick (blood draw using a lancet) in their home. It is possible that up to four finger sticks (two per examiner) will be done. We request a \$60 dollar remuneration for participants in this pilot study, to be given at the conclusion of the in-home portion of the HMHS, in order to show appreciation for their contributions of additional time, physical examinations, 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.

The Health Measures at Home Study has been budgeted for 1 hour 32 minutes per respondent. Twenty-six minutes are for the MEC exam portion of this study and 66 minutes are for the home exam portion of the study. We will test for approximately twelve weeks, at two NHANES locations. The maximum number of respondents is 130 (ages 18+) and the maximum burden is 199 hours (130 respondents \*1.53 hours = 199 hours).

The total burden is 199 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. Health Measures at Home Study