

**National Health and Nutrition Examination Survey**

**OMB No. 0920-0237**

(Expires November 30, 2012)

**Change to Conduct Pilot Testing on New NHANES 2013-14 Content**

**Contact Information**

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Supporting Statement (Change)  
National Health and Nutrition Examination Survey (0920-0237)

This is a request for a non-substantive change to the generic approval of 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 methodological studies and pilot tests for content planned for the 2013-14 NHANES. Burden for these projects has already been approved; thus, no change to the burden is requested.

The studies planned include the following:

- 1) Examination Center Component Testing
  - a) Feasibility Study to Identify Physical Activity and Fitness Tests for Children and Adolescents for Inclusion in the National Health and Nutrition Examination Survey (NHANES) (ages 3-15)
  - b) Oral Health – Dental Fluorosis Imaging/Examination Feasibility Study (ages 12-16)
- 2) Laboratory data collection
  - a) The 24 Hour Urine Sodium Calibration Study (ages 20 and older)
- 3) NHANES 2005-2010 Follow-up Study
  - a) Birth Certificate Linkage Study - NHANES 2005-2010 Children (ages 5-10)

A. Justification

1. Circumstances Making the Collection of Information Necessary.

In section B, page 14 of the approved supporting statement we said the following about these studies under the subheading *Tests of Procedures or Methods to be Undertaken*: “To incorporate new content in future years of the continuous NHANES, evaluation of objective data collection procedures used in other studies and pilot testing of new procedures concurrent to NHANES data collection will be required.”

2. Purpose and Use of the Information Collection

The purposes and uses of each study are detailed below:

a. 2011 Examination Center Components

- i) Feasibility Study to Identify Physical Activity and Fitness Tests for Children and Adolescents for Inclusion in the National Health and Nutrition Examination Survey (NHANES) (ages 3-15)

The Division of Health and Nutrition Examination Statistics (DHANES) has received funds from the Department of Health and Human Services for a feasibility study to identify tests that could be included in the NHANES mobile examination centers, to collect nationally representative data on physical activity and fitness in children and adolescents ages 3-15 years. This feasibility study will be conducted using 400 paid volunteers, who are not participants in NHANES. The physical activity and fitness data to be collected in NHANES would be combined with questionnaire data and data on body composition, body mass index, and nutritional biochemistries to provide a comprehensive picture of the physical health of children in the U.S. One out of every three children in the U.S. is now overweight or obese, a condition that places them at greater risk of developing diabetes, heart disease, and cancer over the course of their lives. Regular physical activity in children and adolescents promotes health and fitness.

The protocol for the Physical Activity and Fitness Test in Children and Adolescents' Feasibility Study, Mobile Examination Center Component is provided in Attachment A.

ii) Oral Health – Dental Fluorosis Imaging/Examination Feasibility Study (ages 12-16)

The purpose of this Fluorosis Study is to assess the information technology pathways needed to capture a set of digital images of anterior upper teeth, deliver those images electronically to a set of readers, receive the scores assigned by readers electronically and validate those scores against the clinical reference exam. A secondary aim is to assess the feasibility of using quantitative light fluorescence imaging (QLF) to adjudicate non-confirmatory results based on the readers' assigned score using a computer algorithm to read a QLF image. This will require comparing the findings from the gold-standard clinical exam (Dean's Index assessment) to the findings determined by the readers and that calculated by the QLF algorithm. Both of these aims will contribute to a long term objective of estimating prevalence of dental fluorosis in the U.S. population within the operational scope of the National Health and Nutrition Examination Survey (NHANES). This study will be conducted using 75 paid volunteers, who are not participants in NHANES. It is estimated that 200 people may need to be screened to get 75 volunteers.

Current national data from the United States indicate an increase in dental fluorosis prevalence in adolescents aged 12-15 years from 22.6% in 1986-87 to 40.7% in 1999-2004. Although the increase in prevalence has occurred primarily in the very mild and mild forms of dental fluorosis, between 3-4% of adolescents had moderate or severe dental fluorosis in 1999-2004. These values are higher than what has been reported from earlier studies.

The protocol for the Oral Health – Dental Fluorosis Imaging/Examination Feasibility Study (ages 12-16) is provided in Attachment B.

b. 2011 Laboratory Data

i. The 24 Hour Urine Sodium Calibration Study (ages 20 and older)  
The objective of this project is to develop calibration equations to estimate 24 hour dietary

sodium intake for the timed and first morning void urine specimens currently collected in the NHANES survey, compared to the gold standard 24 hour urine collection.

Paid volunteers, who are not NHANES participants, will be recruited to collect urine for 24 hours and provide a corresponding dietary recall. Initial recruitment will occur via telephone. Four hundred volunteers will be recruited. From among these 400 volunteers, a subsample of 133 volunteers will be asked to also collect a second 24 hour urine (and corresponding dietary recall) 4-10 days after the first collection. It is anticipated that to get volunteers to adhere to this demanding protocol, a remuneration for each collection will be required.

The protocol for the 24 Hour Urine Sodium Calibration Study (ages 20 and older) is provided in Attachment C.

c. NHANES 2005-2010 Follow-up Study

i. Birth Certificate Linkage Study - NHANES 2005-2010 Children (ages 5-10)

NCHS will be obtaining copies of birth certificates for children examined during the NHANES 2005-2010 in order to link abstracted information from the birth certificates to the extensive biomedical and demographic measures from NHANES. This allows for the examination of factors that influence health and development for children using data from more than one point in time. Doing so adds a longitudinal aspect to NHANES data. Having this additional information helps increase the scientific value and utility of existing NHANES data without the cost or time burden associated with traditional longitudinal studies. Possible data applications include disease or condition prevalence, risk factors, nutrition monitoring, anthropometry, growth and development, and disease monitoring related issues.

Parental consent to link to administrative records, such as birth certificates, was obtained when these children were originally in NHANES. Re-contacting these families is therefore not needed to do this study. There are an estimated 3,800 NHANES children for which birth certificate linkage could be done. There are 50 states, 2 local areas and 5 U.S. territory vital statistics departments that could be contacted. Therefore there are 57 possible respondents (vital statistics representatives).

The protocol for the Birth Certificate Linkage Study – NHANES 2005-2010 Children (ages 5-10) is provided in Attachment D.

9. Explanation of any payment or gift to respondents.

Participants in the Feasibility Study to Identify Physical Activity and Fitness Tests for Children and Adolescents for Inclusion in the National Health and Nutrition Examination Survey (NHANES) (ages 3-15) will be paid 20 dollars for their participation in the study. An additional 30 dollars will be given to the participant's parent on the day of the exam. Checks for an additional forty dollars will be mailed to the parents of respondents who return the physical activity monitor to the data collection contractor. Respondents will be reimbursed for transportation costs.

Participants in the Oral Health – Dental Fluorosis Imaging/Examination Feasibility Study (ages 12-16) will be paid twenty-five dollars.

Participants in the 24 Hour Urine Sodium Calibration Study (20 and older) will be paid \$125 for each complete collection (24 hour urine and a corresponding dietary recall). Those who submit two 24 hours samples will be paid for each collection.

There will not be any re-contact of NHANES 2005-2010 sample children or their parents, so there will not be any respondent gifts or payments. U.S. states, local areas, or territories participating in the birth certificate linkage study will receive payment for linkage activities based on what is the norm for state/local area/territory vital statistics departments to review and approve requests and provide a copy of the birth certificate.

#### 12. Estimates of Annualized Burden Hours and Cost.

The Children's Physical Activity Feasibility Study has been budgeted for 1.5 hours. We will conduct the feasibility study at one NHANES location. However, the project involves paid volunteers, not NHANES participants. The maximum number of respondents would be 400 (ages 3-15) and the maximum burden hours would be 600 (400 respondents \* 1.5 hours = 600 hours).

The Oral Health – Dental Fluorosis Imaging/Examination Feasibility Study (ages 12-16) has been budgeted for 30 minutes for people agreeing to be in the study and 2 minutes for people who are screened but decline or are not eligible to be in the study. We anticipate screening 200 people to get 75 volunteers. We will pilot test for approximately one week at the NHANES mini Mobile Exam Center, which will be located in the parking lot of the contractor's local office. The target number of respondents would be 75 (ages 12-16) and the burden for this group 37.5 hours (75 respondents\*(30/60 hour) = 37.5 hours). For the 125 estimated people who would be screened, but not participate, the burden would be 4.2 hours (125 non participants \* (2/60 hour) = 4.2 hours). The maximum burden for this project would therefore be 41.7 hours.

The 24 Hour Urine Sodium Calibration Study (ages 20 and older) has been budgeted for 2.5 hours for those providing one urine and recall, and 5 hours for those providing two of each. The data will be collected at the NHANES data collection contractor's local office. The maximum number of respondents would be 400 (ages 20 and older) and the maximum burden 1,332.5 hours (400 respondents\*(2.5 hours) + (133 repeat respondents\*2.5 hours) = 1,332.5).

The Birth Certificate Linkage Study - NHANES 2005-2010 Children (ages 5-10) has been budgeted for 2 minutes per electronic record retrieved per linkage official at the various states/local areas/territories. There are 57 state/local area/territory vital statistics departments that the birth certificates could potentially come from. Thus, the maximum number of respondents would be 57. There are 3,800 children for whom records linkage could be done. The project is estimated to last two years. This results in an average number of responses per respondent of 33 per year. Therefore, the maximum annual burden is 63.3 hours (57 respondents\*(2/60 hour) \* 33 responses per representative per year).

The total burden is 2038 hours. This time was already budgeted and approved in line 2. - special

study/pretest participants, 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 Feasibility Study to Identify Physical Activity and Fitness Tests for Children and Adolescents protocol
- B. Oral health – dental fluorosis imaging/examination feasibility study protocol
- C. 24 Hour Urine Sodium Calibration Study protocol
- D. Birth Certificate Linkage Study - NHANES 2005-2010 Children