

National Health and Nutrition Examination Survey

OMB No. 0920-0237

(Expires December 31, 2011)

Request to Conduct Pilot Testing on New NHANES 2009-10 Content

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

This is a request for approval of generic information collections under 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 methodological studies and pilot tests for content planned for the 2011-12 NHANES. General approval and burden hours for these projects have already been approved; thus, no change to the burden is requested.

The methodological studies and pilot tests planned include the following:

Pre examination methodological data collection

- i. Text Messaging Pilot Study (ages 12+)

Pilot tests of 2011-12 Examination Center Components:

- ii. Cognitive Functioning (ages 60+)
- iii. Oral Health (ages 2+)
- iv. Pubertal Maturation (ages 8-18)
- v. Muscle Strength (ages 6+)
- vi. Sagittal Abdominal Diameter (SAD) (ages 8+)
- vii. Creatinine Phosphokinase (ages 12+)
- viii. Chemosensory Variation and Impairment (ages 40+)

Post examination methodological data collection:

- ix. Physical Activity Monitor (PAM) (ages 6+)
- x. 24 Hour Urine Sodium Validation Study (ages 20-79)

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 each pilot or special study are detailed below. Pilot tests will include NHANES participants. Special studies may include NHANES participants, or if not feasible to do in the NHANES setting, they may include paid volunteers. Beginning with the 2011-12 cycle, NHANES will oversample Asians. Since NHANES 2010 does not oversample Asians, pilot tests and special studies may also include additional, non NHANES volunteers drawn from the Asian community. Participation is voluntary for both NHANES respondents and non NHANES volunteers.

a. Pre examination data collection

i. Text Messaging Pilot (ages 12+)

Cell phone usage has increased dramatically over the past decade. In fact, recent data show that wireless-only households make up 14.7% of U.S. households. Text messaging has been used as a communication tool in public health settings for smoking cessation programs, and patient management and health promotion in sexually transmitted disease clinics. Research has also shown that text messaging is an effective way to improve attendance in primary care clinics.

NHANES participants aged 12 and older who are assigned to the morning examination session are asked to fast. Reminder letters and phone calls are supposed to reinforce the fasting instructions. Administrative data have shown that these efforts are not achieving desired results. Between 2004 and 2008, the fasting noncompliance increased from 8.7% to 20.4%. A retraining of all field staff on the importance of conveying instructions on fasting was conducted in June 2008. In the following year, the fasting noncompliance was lower, 12.1%.

Since sexually transmitted disease testing started in 1999 there has also been a general decline in the proportion of participants who receive test results. Ten years of administrative data has shown that the proportion of participants, who received STD test results by calling a designated

toll-free telephone line, declined from 69% to 58%. Current protocol procedures allow the NHANES program to send up to three reminder letters to adults who have not called. The protocol also allows NHANES program staff to call teenagers ages 14-17 years, who have not called for results. The NHANES program makes three attempts to reach teenagers. The telephone number called is usually to a household land line. When teenagers are not home, a message is left with a family member or on an answering machine.

The NHANES program proposes to study text messaging as a communication tool to achieve the following objectives:

- To ask if respondents have a cell phone, and if so, to obtain permission to text them
- To reduce fasting noncompliance by sending out a text message reminder to fast, for respondents with cell phones who agree to receiving text messages
- To improve the communication of STD test results by text messaging a reminder to call for results, to respondents with cell phones who agree to receiving text messages

The protocol for the Text Messaging pilot study is provided in Attachment A.

b. Pilot test of 2011 Examination Center Components

i. Cognitive Functioning (ages 60+)

The Cognitive Functioning component was proposed by the Healthy Aging Program, Division of Adult and Community Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC). Cognitive functioning was assessed in NHANES 1999-2002 during the household interview portion of the survey, and as an examination component in NHANES III (1988-94).

The addition of a cognitive functioning component in the mobile examination center has tremendous public health relevance and would enhance the overall utility of NHANES data. An assessment of cognitive functioning of older adults is useful to include because it is an important risk factor for loss of independence, institutionalization and mortality in this group. Additionally, its inclusion in NHANES provides the ability to investigate prevalence and co-morbidities of declining cognitive functioning with other self-reported and objective physical measures.

The protocol for the cognitive functioning pilot study is provided in Attachment B.

ii. Oral Health (ages 2+)

An oral health examination is part of the current NHANES. NHANES oral health data has been used to track *Healthy People* 2010 oral health objectives. In an effort to continue to serve the *Healthy People* initiative and to better serve national and state information needs, the Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion has proposed modifications to the NHANES oral health protocol. The National Institute of Health / National Institute of Dental and Craniofacial Research is also a collaborator for this component. A main goal of these changes is to improve surveillance of dental caries, particularly in children.

For 2011-12, the oral health component will be modified to:

- Return to using dentists as examiners, rather than technicians
- Replace the Basic Screening Exam (BSE) with:
 - Tooth Count assessment on all ages 2+
 - Comprehensive Dental Caries assessment on all ages 2+
 - Dental Sealant assessment on ages 2-29 years
 - Dental Fluorosis assessment on ages 6-29 years
- Continue with
 - Comprehensive Periodontal Exam for adults aged 30+
 - Medical Exclusion Questions for adults aged 30+
 - Recommendation for Care / Referral

The protocol for the oral health component is provided in Attachment C.

iii. Pubertal Maturation (ages 8-18)

The addition of the pubertal maturation questions has tremendous public health relevance and would improve the utility of NHANES clinical, biomarker, and questionnaire data. Information on pubertal maturation status is useful to include in NHANES because the endocrine changes manifested in secondary sexual characteristics underlie many physiological changes during puberty. Sexual development correlates more closely with physical changes such as height, weight, bone density and certain biochemical markers than chronological age, thus facilitating assessment of bone health, body composition, and iron status in pre-adolescence and adolescence. Sexual maturation may be more closely related to other aspects of adolescent development and experience, from cognitive performance, to self-perceptions, to psychosocial behavior than to other physiologic changes. Furthermore, early sexual maturity has been found to closely correlate with self-image and sexual behaviors, which are also included in the Mobile Examination Center (MEC) interview.

A validation study at Children's Hospital National Medical Center (CNMC), Washington, DC was conducted from March to August 2009. The study showed that the audio computer-assisted self-interview (ACASI) method is a feasible method of pubertal maturation self-assessment for youth as young as 8 years of age. The method demonstrated good to excellent agreement between boys and examiners in genital stage and pubic hair assessment and excellent agreement between girls and examiners in breast stage and pubic hair assessment when comparing physical examination results to self assessment. Over three-fourths of the participants thought it was easy to choose a drawing and almost 100% found the computer easy to use.

The protocol for the Pubertal Maturation Pilot Study Mobile Examination Center Component is provided in Attachment D.

Attachment E contains the ACASI screen shots, including both question text and images shown, for this component. Children 8-9 years of age see 4 drawings for each body site. Children and teens, 10 years and older, see all 5 Tanner stages of maturation.

iv. Muscle Strength (ages 6+)

The recent Physical Activity Guidelines for Americans (2008) recommends that adults complete muscle strengthening activities in conjunction with general recommendations to obtain 150 minutes or more of physical activity a week. Similar guidelines exist for school age children. Recent studies indicate the relative importance of muscular strength, and its independence from aerobic fitness, to impart health benefits. These benefits include lowered relative risk of all cause and cancer specific mortality and lower relative risk of conditions and putative mechanisms that may underpin the association between muscular strength and all cause mortality.

Upper body muscle strength testing, using a handgrip test, was done in HES III for adolescents 12-17. Lower body muscle strength testing was done in the NHANES 1999-2002, but only for participants aged 50+. The proposed muscular strength measurements for 2011-12 include the following two tests, to be done in the Mobile Examination Center (MEC):

- handgrip dynamometer assessment will be used to assess upper body strength
- lower body (quadriceps/hamstring) strength assessment using a dynamometer placed at the lower shin of the participants.

This is the first time both these tests will be done for participants 6 years and older, in our survey.

The protocol for muscle strength pilot is provided in Attachment F.

v. Sagittal Abdominal Diameter (SAD) (ages 8+)

The simple description of obesity has traditionally depended on body mass index, a marker of relative weight. However, estimates of trunk fat, especially fat in the visceral (intra-abdominal) deposits are usually better correlated than body mass index with established physiological risk factors for chronic disease. Favorable experience with measurement of waist circumference demonstrates this point. Recent studies, however, suggest that the supine sagittal abdominal diameter (SAD) may offer yet a better method for estimating the aspect of obesity most relevant to the risk of diabetes, cardiovascular disease, and perhaps other conditions.

Epidemiologic and clinical applications of the SAD measurement are hampered by a lack of reference data based on a representative US population. Using a low-cost, sliding-beam caliper, NHANES can accumulate population-based reference data. The target group for this measurement includes males and females, age 8 years and older.

The protocol for the Supine Sagittal Abdominal Diameter pilot is provided in Attachment G.

vi. Creatinine Phosphokinase (CPK) (ages 12+)

Laboratory testing for the muscle enzyme CPK was added to the routine NHANES Biochemistry Profile in 2009. To make this laboratory data more useful, a short series of questions is proposed to supplement laboratory data collection in order to make the test results more directly interpretable. This would help provide better background prevalence estimates for CPK levels in the general population, and help establish more optimal CPK normal reference ranges.

Specifically, the questions would ask whether the examinee has, in the 3 day period immediately prior to specimen collection, had an acute injury or performed strenuous exercise, or whether the person has a history of chronic muscle pain. These are all factors that could elevate CPK levels.

The protocol and questionnaire for the Creatinine Phosphokinase pilot is provided in Attachment H.

vii. Chemosensory Variation and Impairment (ages 40+)

In the healthy normal population, both acquired and genetic variation in taste and smell may affect food preferences and hence long term risk of obesity and other medical problems. Also, acquired nutritional deficits may be more prevalent in older persons with olfactory deficits. Age-related changes in flavor perception may contribute to changes in food palatability and nutritional intake. Individuals with chemosensory impairments may also be at increased risk to their safety, from fire and gas leaks or explosions.

Smell testing will be performed using the Brief Smell Identification Test (BSIT- also known as the CC-SIT) which is a well standardized "scratch and sniff" smell identification test. Taste testing will be performed by having the examinee taste a small amount of a test substance (sweet, sour, bitter, salty, etc) to determine if they can correctly identify the taste.

The protocol for the Chemosensory Variation and Impairment pilot is provided in Attachment I.

c. Post examination data collection

i. Physical Activity Monitor (PAM) (ages 6+)

The recent release of the Physical Activity Guidelines for Americans has focused greater attention on physical activity and its impact on health. It is proposed that a Physical Activity Monitor (PAM) component be added back into NHANES. NHANES has not had a PAM component since its 2003-2006 cycles. Adding a PAM component back into NHANES will provide an opportunity to examine secular changes in physical activity behavior in the nation. Furthermore, advances in technology allow us to collect improved data that will be a more complete assessment of daily physical activity. In 2003-2006 the PAM device was worn on the waist using a belt and had to be removed for bathing purposes. The new device is worn on the wrist. Because it is waterproof, it will not need to be removed. In addition to monitoring physical activity, this new device will also allow for data collection concerning patterns of sleep.

The protocol for post-examination Physical Activity Monitor (PAM) is provided in Attachment J.

ii. 24 Hour Urine Sodium Validation Study (ages 20-79)

Sodium consumption in the US population is well above recommended limits. It is widely believed that the high sodium intake may be partially responsible for the high prevalence of hypertension in the US population. Efforts on many fronts in the public health community are

targeting a reduction in sodium in the food supply. NHANES monitors the dietary intake of the US but dietary recalls are considered inadequate measures of dietary sodium intake at this time. Urinary excretion better characterizes sodium consumption but is extremely variable. Several studies have concluded that casual urine samples correlate sufficiently with 24 hour urine collections to allow for monitoring population intake of sodium. NHANES currently collects two urine specimens under conditions more rigid than 'casual'. One is a timed urine collection and the second is the first morning void. To assess the ability of NHANES to monitor population sodium intake with its current urine protocol, a 24 hour urine validation study is necessary.

This study will be conducted among paid volunteers ages 20-79 (with 1/3 in each of these age groups—20-39-40-59, 60-79), equal numbers of both genders, and including non-Hispanic Blacks and the Hispanic population.

The protocol for post-examination 24 Hour Urine Sodium Validation Study is provided in Attachment K.

9. Explanation of any payment or gift to respondents.

The examination center pilot tests will not involve any additional remuneration to NHANES participants. Paid volunteers (i.e. non-NHANES respondents) used to supplement pilot or special study activities, and NHANES respondents participating in post exam data collections, other than the 24 hour urine, will be remunerated \$25. Remuneration for volunteer participants for the 24 hour urine collection are explained below.

Participants in the sodium urine collection study will be asked to collect their urine for 24 hours. Those willing to participate will be asked to come to a central location, the NHANES home office, for instructions, supplies, a venipuncture, height, weight and blood pressures measurements and an initial dietary recall. After urine collection, participants will return specimens to the NHANES home office and do a dietary recall for the 24 hours that the urine was collected. More specifically, we are asking people to leave their homes twice to come to a central location, the NHANES home office. We are asking participants to take two dietary recalls. In addition, to accurately validate the NHANES urine collection modalities the 24 hour urine can't be collected in one container. Because NHANES collects its urines both throughout the day and evening and collects a first morning void, participants will be asked to keep each void in a separate container and label that container with the collection time. That means that if they urinate 8 times in 24 hours they will need to transport back 8 urine specimens. The 24-hour urine collection requires that you not miss any urine when you are having a bowel movement, when you are working, when you leave the house, etc. so people generally stay home for the collection, which is not insignificant. For women, the collection must be scheduled to avoid menstruation. In a study without separate specimens, no dietary recalls and where the participant is visited at their household rather than asked to come to a central location, the remuneration is \$90. Because of the increased complexity of the NHANES 24 hour urine collection requirement our participants will be remunerated \$200 dollars. Remuneration will be given to participants after the urine samples are returned the NHANES home office and the dietary recall has been conducted.

12. Estimates of Annualized Burden Hours and Cost.

There are no additional burden hours requested. The table below describes the number of respondents and burden for each specific test being performed.

Burden category	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total respondent burden (hours)
7. Follow-up and Special Studies (Listed by Attachment Letter)				
A. Text Messaging	1183	1	2/60	39
B. Cognitive Functioning	150	1	10/60	25
C. Oral Health	315	1	10/60	53
D. Pubertal Maturation	118	1	4/60	8
F. Muscle Strength	648	1	16/60	173
G. Sagittal Abdominal Diameter	523	1	5/60	44
H. Creatinine Phosphokinase	1420	1	2/60	47
I. Chemosensory Variation and Impairment	546	1	10/60	91
J. Physical Activity Monitor	548	1	5/60	46
K. 24 Hour Urine Sodium	444	1	1.5	666
Total				1192

Pilot tests of 2011-12 Components

The details of each test are shown below.

The Text messaging pilot has been budgeted for 2 minutes. We will pilot test for 20 weeks, at

five NHANES PSUs. The maximum number of respondents would be 1183 (ages 12+) and the maximum burden 39 hours (1183 respondents * 2/60 hour = 39 hours).

The Cognitive Functioning pilot has been budgeted for 10 minutes. We will pilot test for 8 weeks at two NHANES PSUs. This pilot will also include approximately 50 paid volunteers. The maximum number of respondents would be 150 (ages 60+) and the maximum burden 25 hours (150 respondents * 10/60 hour = 25 hours).

The Oral Health pilot has been budgeted for 10 minutes. We will pilot test at two NHANES PSUs. The maximum number of respondents would be 315 (ages 2+) and the maximum burden 53 hours (315 respondents* 10/60 hour = 53 hours).

The Pubertal Maturation pilot study has been budgeted for 4 minutes. We will test for a total of eight weeks, across two NHANES PSUs (four weeks per location, 59 respondents per location). The maximum number of respondents would be 118 (ages 8-18) and the maximum burden 8 hours (118 respondents *4/60 hour = 8 hours).

The Muscle Strength pilot study has been budgeted for 16 minutes. We will test for a total of 8 weeks, across two NHANES PSUs. This pilot will also include approximately 100 paid volunteers. The maximum number of respondents would be 648 (ages 6+) and the maximum burden 100 hours (648 respondents * 16/60 hours = 173 hours).

The Sagittal Abdominal Diameter (SAD) pilot study has been budgeted for 5 minutes. We will test for a total of 8 weeks, across two NHANES PSUs. The maximum number of respondents would be 523 (ages 8+) and the maximum burden 44 hours (523 Respondents * 5/60 = 44 hours).

The Creatinine Phosphokinase pilot study has been budgeted for 2 minutes. We will test for a total of 24 weeks, across six NHANES PSUs. The maximum number of respondents would be 1420 (ages 12+) and the maximum burden 44 hours (1420 Respondents * 2/60 = 47 hours).

Chemosensory Variation and Impairment pilot study has been budgeted for 10 minutes. We will test for a total of 16 weeks, across four NHANES PSUs. The maximum number of respondents would be 546 (ages 40+) and the maximum burden 44 hours (546 Respondents * 10/60 = 91 hours).

The Physical Activity Monitor pilot study has been budgeted for 5 minutes. We will test for a total of 8 weeks, across two NHANES PSUs. The maximum number of respondents would be 548 (ages 6+) and the maximum burden 46 hours (548 Respondents * 5/60 hours = 46 hours).

The 24 Hour Urine Sodium Validation Study has been budgeted for 1.5 hours. We will test a total of 444 paid volunteers, at a central NHANES location (not the MEC). The maximum number of respondents would be 444 (ages 20-79), with 1/3 in each of these age groups—20-39-40-59, 60-79, equal numbers of both genders, and including non-Hispanic Blacks, Asians and the Hispanic population. The maximum burden would be 740 hours (444 Respondents * 1.5 hours = 666 hours).

The total burden is 1192 hours. This time was already budgeted and approved in line 2, 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 Text Messaging Study
- B. Protocol for Cognitive Functioning Pilot Study
- C. Protocol for Oral Health Pilot Study
- D. Protocol for Pubertal Maturation Pilot Study
- E. Pubertal Maturation Screen Shots
- F. Protocol for Muscle Strength Pilot Study
- G. Protocol for Sagittal Abdominal Diameter Pilot Study
- H. Protocol for Creatinine Phosphokinase (CPK) Pilot Study
- I. Protocol for Chemosensory Variation and Impairment Pilot Study
- J. Protocol for Physical Activity Monitor (PAM) Pilot Study
- K. Protocol for 24 Hour Urine Sodium Validation Study Pilot Study