

National Health and Nutrition Examination Survey

OMB No. 0920-0237

(Expires November 30, 2009)

**Change to Conduct Methodological Studies and Pilot Testing on
Planned New 2009-10 NHANES Questionnaire Sections**

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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 approval of the National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0237, exp. November 30, 2009), 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 2009-10 NHANES. Burden for these projects has already been approved; thus, no change to the burden is requested.

The NHANES Conditions of Approval stated the following: “With respect to conducting any pilot or nonresponse studies, OMB should be provided with a formal request that describes the specific study design, need for the information, and response burden. OMB will respond within three weeks indicating approval, disapproval, or passback exchanges seeking further information. No pilot or nonresponse studies should be conducted without receipt of approval from OMB.”

The methodological studies planned include the following:

- 1) Cognitive testing of 4 sets of questions.
 - a) Reactions to Race Questionnaire (6 questions)
 - b) Dietary Screener Questionnaire (26 questions)
 - c) Consumer Behavior Questionnaire (10 questions)
 - d) Inflammatory arthritis Questionnaire (30 questions)
- 2) Pilot tests of 2009 Examination Center Components
 - a) Reactions to Race Questionnaire (ages 18+)
 - b) Dietary Screener Questionnaire (ages 12+)
 - c) Inflammatory Arthritis Examination (ages 20-69)
- 3) Household/telephone questionnaire field tests of new content
 - a) Dietary Screener Questionnaire (proxy ages 2-11)
 - b) Consumer behavior Questionnaire (ages 16+)
 - c) Inflammatory Arthritis Questionnaire (ages 20-69)
 - d) Oral Health Questionnaire (ages 30+)
- 4) Methodological test comparing NHANES Oral Health Examination to Canadian Health Measures Survey Oral Health Examination
- 5) Validation of Pubertal Maturation self administered module

A. Justification

1. Circumstances Making the Collection of Information Necessary.

In section B, page 57 of the approved supporting statement we said the following about these methodological studies under the subheading ‘Pilot Testing for 2009-2010’.

“All pilot/feasibility testing must be concurrent to the ongoing data collection within the framework of the survey. DHANES proposes continuing to pilot test the procedures for 2009-2010 as we have done in 2006 for 2007-2008. We plan to start the piloting and developing methods in the spring of 2007.”

2. Purpose and Use of the Information Collection

The purposes and uses of each methodological/pilot study are detailed below.

A. Cognitive testing of 4 sets of questions.

NHANES’ respondents will not be involved in the cognitive testing. Paid volunteers will be recruited of various ages and race-ethnicities. When the target population is the same all five sections will be tested on the same individual.

i. Reactions to Race Questionnaire

Since 2002, the Behavioral Risk Factor Surveillance System (BRFSS) Reactions to Race is available for use as an optional module by all states and territories, and a total of 16 states have experience with the module, including three states that have used it multiple years. The 6 questions include assessments of socially-classified “race” (“How do other people usually classify you in this country?”), “race”-consciousness (“How often do you think about your race?”), perceptions of differential treatment at work and when seeking health care, and experiences of physical symptoms and of emotional upset as a result of “race”-based treatment. The module was developed by the Measures of Racism Working Group at the Centers for Disease Control and Prevention.

BRFSS is a telephone-based interview survey, conducted at the state level. Since NHANES is an examination survey, conducted on a national level, it is necessary to test the feasibility of using this questionnaire in the NHANES setting. This proposed cognitive testing is designed to evaluate the reactions to race module (see Attachment 1) through in-depth interviews. In addition to the responses to the questionnaire, the cognitive testing will reveal the participants’ understanding of the wording of the questions and their decision making process when answering these questions.

To date, analysis of these questions on the BRFSS has been associated with self reported differences in reported health. Inclusion of the proposed questions on the 2009-2010 cycle of NHANES will enhance understanding of how reactions to “race” impact may impact objective measures of risk factors and conditions, and may provide insight into the underlying causes of observed “racial”/ethnic health disparities.

There are two goals of this proposed study. The first goal is to assess how well the meaning of the questions, in the reactions to race module, are understood by potential participants. The second goal is to assess the appropriateness of the wording used in the module in both English

and Spanish. Both of these goals will contribute to a long term objectives of enhancing the understanding of how reactions to “race” impact health. This understanding may provide insight into the underlying causes of observed “racial”/ethnic health disparities.

Although the “Reactions to Race” module underwent three rounds of cognitive testing and small-scale pilot testing by the Research Triangle Institute in the summer of 2001 and was piloted on the 2002 (BRFSS) by six states NHANES requires more extensive testing in English and Spanish of respondents similar to those sampled in NHANES.

Two rounds of cognitive testing may occur depending on the results of the first round. This cognitive study will be followed by pilot testing later in 2008.

ii. Dietary Screener Questionnaire

The Dietary Screener Module consists of 26 questions (Attachment 2) assessing participants’ intake of fruits and vegetables, fiber, added sugar, dairy/calcium, whole grains, solid fats, red meat and processed meat. These were chosen because they are implicated in chronic disease etiology, they are targets of dietary guidance, they are potential or current targets for nutrition interventions, and they are current or potential targets for policy changes (e.g. eliminating soda in schools initiatives), and thus also have great potential to evaluate changes in dietary intake due to policy changes. Inclusion of a screener into NHANES (a nationally representative survey that also includes multiple 24 Hour Dietary Recalls (24HR)) would allow the screener to be calibrated and the resulting scoring algorithms to be used in smaller studies to compare to national estimates. In situations where the 24HR is not feasible, the availability of such an instrument and its scoring algorithms would enable the public health community to conduct smaller more localized surveys at relatively little cost to derive estimates of intake and also to compare these estimates with national dietary intakes. Potential users are state and county health departments, and others conducting health research, for a variety of purposes, including identifying subgroups of the population most in need of targeted interventions, relating individual data to ecological data, and incorporating dietary measures within ongoing health studies. The module was developed by the National Cancer Institute.

The proposed cognitive testing is designed to evaluate the Dietary Screener Module through in-depth interviews. In addition to the responses to the questionnaire, the cognitive testing will reveal the participants’ understanding of the wording of the questions and their decision process in answering these questions. The results from the test will be used to assess and improve the instrument’s validity and determine the feasibility of inclusion in NHANES starting in 2009.

Several rounds of cognitive interviewing (including three in Spanish) have previously been conducted on this instrument, therefore only one round is planned before inclusion in NHANES.

iii. Consumer Behavior Questionnaire

Since 2005 NHANES has contained a subset of questions referred to as the Flexible Consumer Behavior Survey (FCBS) sponsored by the Economic Research Service of the USDA. For 2009 10 new questions (Attachment 3) are proposed to gather additional information about nutrition

knowledge, attitudes, and beliefs. This contributes to the major NHANES objectives of studying the relationship between diet, nutrition and health, as well as monitoring trends in risk behaviors and the prevalence of risk factors in population subgroups.

These new questions cover two subject areas: Food labels and organic foods. The food label questions are a follow up to the current food label question which asked if individuals use food labels. Depending on the answer to that question individuals will be asked why they do or don't use food labels. Because little is currently known on this subject an open ended question will be used during the cognitive and future pilot testing. It is hoped that after the cognitive and pilot testing that response categories may be determined for the 2009 NHANES. Seven of the 8 organic food questions will be asked only of those saying they use organic foods on a question already on the NHANES. The 8th is an assessment of the awareness of the USDA Organic Seal.

It is anticipated that the organic questions are so straightforward that only one round of cognitive interviewing would be required. Because of the general lack of knowledge about why people do and do not use food labels two rounds of cognitive testing are planned.

iv. Inflammatory Arthritis Questionnaire

The Inflammatory Arthritis Questionnaire (Attachment 4) is a companion to the proposed Inflammatory Back Pain Examination component. The purpose and use of the data are common for both the questionnaire and examination. The goal of 2009 NHANES Inflammatory Back Pain proposal is to assess the general prevalence of Inflammatory Back Pain and the prevalence of Spondyloarthritis in the US general population of adults. This will be the first US national survey of this important, treatable disorder, for which new, effective treatments have recently for the first time become available. The NHANES work will contribute to a long term objective of reducing the population burden of Spondyloarthritis, which is the third most common form of arthritis affecting adults.

The corresponding questionnaire consists of 36 questions. The target ages are 20-69. Many of the questions are targeted only to those with back pain. Several of the questions are existing NHANES questions about arthritis and psoriasis that will be rearranged to be in this module.

Because this is the first survey use of many of these questions two rounds of cognitive interviewing are planned before the field testing.

B. Pilot test of 2009 Examination Center Components

All pilot tests will occur in the NHANES Mobile Examination Center (MEC) on NHANES participants. They will be staggered over the interval from March through November, 2008 so that only one pilot test is occurring at the same PSU.

i. Reactions to Race Questionnaire (ages 18+)

See Section 2.A.i. for the purpose of the BRFSS Reactions to Race Questionnaire cognitive testing. The results of the cognitive testing will be used to determine if any changes are needed

to improve the questions and if all questions are acceptable for pilot testing. After the February 2008 cognitive testing process has been completed, the pilot study for these questions will be conducted in a Division of Health and Nutrition Examination Surveys' (DHANES) trailer.

During the pilot test in the DHANES trailer, the reactions to race questions will be administered using the audio computer-assisted self-interviewing (ACASI) system. This ACASI system will be the same as what is currently used in the DHANES trailers to ask sensitive questions, such as reproductive health and illegal drug use.

The questions are in Attachment 5 Reactions to Race pilot test.

ii. Dietary Screener Questionnaire

See Section 2.A.ii. for the purpose of the Dietary Screener Questionnaire. The Questionnaire will be pilot tested at one NHANES PSU with a variety of respondents. Respondents 12 and older will answer the questions during the Mobile Examination Center CAPI interview. Respondents for 2-11 year olds will have a field test of the questions during one NHANES PSU (not necessarily the same PSU as the MEC CAPI pilot test).

The Dietary Screener Questionnaire pilot test is in Attachment 6.

iii. Inflammatory Arthritis Examination pilot test

The protocol for the examination component is in Attachment 7. Spondyloarthritis, or spinal arthritis, is thought to be the third most common form of arthritis among adults after Osteoarthritis and Rheumatoid arthritis. Historically, comparatively little attention has been paid to Spondyloarthritis, as opposed to other forms of arthritis, and there have been no definitive U.S. population based survey of its prevalence, demographic distribution and overall burden. Recently, because of the development of new, effective drug treatments, it has become clear that developing accurate population based data will be a key component of the medical and public health agenda to reduce the burden of this significant health problem. The NHANES Spondyloarthritis survey is specifically designed to address this issue. The NHANES program intends to begin a Spondyloarthritis survey in January of 2009. To ensure proper integration of the component with the current NHANES protocol, developmental work and a pilot test in the interval from February-August 31, 2008 are proposed.

C. Household/telephone questionnaire field test of questionnaires.

The following 4 sections of the questionnaire will be tested during two NHANES PSUs. The purpose of the field test is to evaluate interviewer training of the questions, programming of the software to collect the information and further evaluation of the understanding of the questions by a broader field of respondents than included in the cognitive testing. As with the MEC testing these will be staggered across several PSUs to minimize the response burden per participant. All of these topics were described in the cognitive testing part 2.A. except the field test of the Oral Health Questionnaire.

- i. Dietary Screener Questionnaire (proxy ages 2-11). See Attachment 8.
- ii. Consumer Behavior Questionnaire (telephone). See Attachment 9.
- iii. Inflammatory Arthritis Questionnaire. See Attachment 10.
- iv. Oral Health Questionnaire. See Attachment 11.

D. Methodological test comparing NHANES examination to Canadian Health Measures Survey

The study will be conducted in a Division of Health and Nutrition Examination Surveys' trailer from June 15, 2008 through July 15, 2008.

The scope of this oral health methodology study is consistent with clinical research designed to assess inter-rater and inter-examiner reliability. Assessing data reliability is an important element in epidemiologic studies using multiple examiners to collect examination data. An objective analysis of the data is based on evaluating examiner performance. The confirmation of data reliability through statistical analyses improves external generalizability of the findings.

A detailed protocol is in Attachment 12.

E. Validation of Pubertal Maturation self administered module

The purpose of the validation study is to compare the results obtained using the "gold standard" physical examination Tanner staging method to results reported by children and teens based on self-assessment. Tanner staging is part of a routine physical examination. Data collection for the validation study will coincide with routine clinic visits. Informed consent will be obtained at the time of the clinic visit. The study will be conducted in conjunction with and at the Children's National Medical Center (CNMC) in Washington, D.C. as soon as it is approved. The NCHS Institutional Review Board (Ethics Review Board (ERB)) and the CNMC Institutional Review Board have approved the validation study protocol and consent materials.

Three attachments are provided describing the details of the study: The Overview of the Validation Study of the Pubertal Maturation self administered module (Attachment 13), the study justification, protocol, and materials), the consent form, assent form (Attachment 13a) and questionnaire (Attachment 13b).

9. Explanation of any payment or gift to respondents.

The examination center pilot tests and the questionnaire field testing will not involve any additional remuneration to the NHANES participants. The recruited volunteers for the cognitive testing, the methodological test comparing NHANES Oral Health Examination to Canadian Health Measures Survey Oral Health Examination, and the Validation of the Pubertal Maturation self administered module and the will be remunerated for their participation as follows:

Cognitive Testing \$50

Oral Health \$50
 Pubertal Maturation \$15

12. Estimates of Annualized Burden Hours and Cost.

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	3,363	1	12/60	683

The details of the number of respondents and burden for each study are summarized below:

Cognitive testing of 4 sets of questions

To the extent possible the cognitive testing will occur for all questions on the same volunteers assuming a 2 hour time commitment per person. We will assume that might not always be possible so we will request the number of respondents be 25% greater than the number of interviews we need. Although not all sections are likely to need 2 rounds of pilot testing we will assume two rounds to allow for the maximum possible respondent burden of 272 hours (68 respondents*2 rounds*2 hours*=272 hours).

Pilot tests of 2009-10 Examination Content Components

The Reactions to Race Questionnaire pilot has been budgeted at 5 minutes per respondent. We will pilot test for a maximum of 2 NHANES PSUs. Therefore the maximum number of respondents would be 600 (ages 20+) and the maximum burden 50 hours (600 respondents*(5/60 hour) =50 hours).

The Dietary Screener Questionnaire pilot has been budgeted for 6 minutes. We will pilot test at 1 NHANES PSU therefore the maximum number of respondents would be 360 (ages 15+) and the maximum burden 36 hours (360 respondents*(6/60 hour) =36 hours).

The Arthritis Examination pilot has been budgeted for 3 minutes. We will pilot test at 1 NHANES PSU therefore the maximum number of respondents would be 270 (ages 20-69) and the maximum burden 13.5 hours (270 respondents*(3/60 hour) =13.5 hours).

Household/telephone questionnaire field tests of new content

The field testing of the household questionnaire sections (Dietary Screener, Oral Health and Inflammatory Arthritis) and telephone questionnaire sections (Consumer Behavior) will occur at a maximum of 2 NHANES PSUs. The estimated burden for these is as follows for a total of 109

hours.

Questionnaire	Maximum number of respondents	Burden in Hours	Total Burden hours
Dietary Screener (2-11 yrs)	190	6/60	19
Consumer Behavior	325	2/60	11
Inflammatory Arthritis	520	5/60	43
Oral Health	540	4/60	36
Total			109

The methodological study comparing the NHANES Oral Health Examination to the Canadian Health Measure Survey's has a planned size of 250 respondents requiring 15 minutes per person for a total burden of 62.5 hours (250 respondents*(15/60)=62.5 hours).

The validation study of the self administered pubertal maturation module has a planned size of 240 respondents requiring 20 minutes per respondent for a total burden of 80 hours (240 respondents*(20/60)=80 hours).

The total burden is 683 hours. This time was budgeted in line 7. Follow-up and Special Studies of the original submission.

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:

- 1 Reactions to Race Questionnaire
- 2 Dietary Screener Questionnaire
- 3 Consumer Behavior Questionnaire
- 4 Inflammatory Arthritis Questionnaire
- 5 Reactions to Race Questionnaire Pilot Test
- 6 Dietary Screener Questionnaire (proxy ages 12+) MEC Pilot Test
- 7 Inflammatory Arthritis Examination (ages 20-69) Pilot Test
- 8 Dietary Screener Questionnaire Household Field Test
- 9 Consumer Behavior Questionnaire Household Field Test
- 10 Inflammatory Arthritis Questionnaire Household Field Test
- 11 Oral Health Questionnaire Household Field Test
- 12 Methodological study comparing NHANES Oral Health Examination to Canadian Health Measures Survey Oral Health Examination
- 13 Overview of Validation Study of Pubertal Maturation self administered module
 - 13a Study justification, protocol, and materials.
 - 13b Self assessment questions.