

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

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

**GenIC to Conduct Pilot Testing/Methodology Studies in NHANES**

**Contact Information**

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This is a request for a GenIC 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 Pilot studies planned include the following:

- 1) Mobile Examination Center (MEC) Testing
  - a) NHANES Human Papillomavirus (HPV) Prevalence Among U.S. Men Pilot Study (ages 14-59)
  - b) NHANES Dental Fluorosis Imaging Project Feasibility Study (ages 6-19)

In addition, we would like to request an NHANES National Youth Fitness Survey (NYFS) remuneration change. No changes are being requested to other aspects of the NYFS. The detailed discussion of this part of the request is found in A.9. Explanation of any payment or gift to respondents.

#### 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. It includes a household interview, done in participants' homes and physical measures and additional interviews done at the NHANES Mobile Examination Center (MEC). There may also be follow-up interviews or components (such as a 2<sup>nd</sup> dietary interview or the physical activity monitor (PAM)) that take place after the MEC exam. 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 study are detailed below. Tests will include NHANES participants or paid volunteers (in circumstances when there aren't enough NHANES participants in the pilot's target group or when the pilot cannot be conducted in the NHANES setting, etc.). Participation is voluntary.

### a. 2012 Mobile Examination Center (MEC) Components

#### i HPV Prevalence Among U.S. Men Pilot Study (ages 14-59)

Prevalence of current infection of HPV in US males is unknown. Prevalence of current infection of HPV via DNA detection is important to measure impact of prophylactic vaccines introduced in 2009. NHANES has collected information on HPV DNA among females using a vaginal swab component since 2002; however, HPV has not been measured in NHANES among men.

The purpose of this additional HPV study is to collect information that will shed light on HPV prevalence in men. The specimen will be self-collected by male survey participants, 14-59 years old. This project is being proposed by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP).

A pilot study was conducted by the University of Hawaii, comparing three methods of self-administered specimen collection compared to physician collected specimens (described in Attachment A). The three different methods evaluated included a regular swab (dry), emery paper or foam swab (dry). This pilot evaluation of self-collection in males found the yield of the specimens similar across methods. The specimen collection is acceptable to the target group; the majority of men were willing to collect the specimen themselves, in private. The regular dry swab method was chosen to use for NHANES purposes.

More details about the HPV Prevalence Among U.S. Men Pilot Study are provided in Attachment A.

#### ii NHANES Dental Fluorosis Imaging Project Feasibility Study (ages 6-19)

Community water fluoridation has been identified as one of the 10 most significant public health achievements in the United States in the past century and water fluoridation is a key disease prevention activity for CDC. Dental fluorosis occurs when an individual has been exposed to higher levels of fluoride during tooth development. Fluorosis is a condition that affects the dental enamel, resulting in mild, white striations in its mildest form, through to brown pitting or even complete loss of the enamel in its most severe forms. It has been shown that there is a relationship between water fluoride concentration and the extent of fluorosis. Even at optimal and suboptimal levels of water fluoride concentration, mild fluorosis may occur.

During the MEC examination, A dual imaging camera will be used to capture a standard polarized white light (PWL) image and a Quantitative light fluorescence (QLF) image of the survey participants' upper six anterior teeth. After the MEC examination, the PWL image will be remotely read by 6 readers who will score each of the upper four anterior incisors using the same guidelines as prescribed for the clinical dental fluorosis assessment, which is currently conducted on NHANES. The QLF image will quantify changes in mineral loss in enamel surface of teeth caused by fluorosis. A complex algorithm will be employed to map out areas of reduced mineralization with respect to sound enamel tissue, followed by a process of subtraction to reveal areas considered as fluorosis.

More details about the NHANES Dental Fluorosis Imaging Project Feasibility Study (ages 6-19) are provided in Attachment B.

9. Explanation of any payment or gift to respondents.

Participants in the Human Papillomavirus (HPV) in Men Pilot Study (ages 14-59) will collect the usual remuneration given to NHANES participants. They will not be given any additional remuneration for their participation in this pilot study.

Participants in the NHANES Dental Fluorosis Imaging Project Feasibility Study (ages 6-19) will collect the usual remuneration given to NHANES participants. They will not be given any additional remuneration for their participation in this pilot study.

We are requesting a modification to the NYFS remuneration level to allow differential remuneration to encourage more parents to bring their children in for weekday examination appointments. Currently weekend slots at a given location are filling up first. We believe this is occurring even with families whose schedules might allow them to attend a weekday appointment. For example, children younger than school age (such as 3 – 5 year olds) are being scheduled on weekends even though they do not attend school yet and therefore would not miss a school day if they attended a weekday exam session. Because the weekend slots are filling first, children who can only come on a weekend (because they are older and cannot miss school, for example) are not able to participate in the survey. This is adversely affecting our ability to get an adequate sample of examined young people. We believe that differential weekday remuneration will lead to interviewers scheduling weekday appointments first, when possible. Then more weekend

appointments can be saved for families who truly are only available on weekends. We propose increasing the remuneration for weekday appointments by \$15.

The current NYFS remunerations for all days are as follows:

Subgroup	NHANES NYFS
12-15	\$60
Under 12	\$40

Under the proposed modification the NYFS remunerations for weekdays would be:

Subgroup	NHANES NYFS
12-15	\$75
Under 12	\$55

This request is in keeping with the strategies discussed in section A9 of the supporting statement for the full NHANES regarding efforts made to maintain and increase response rates. Specifically this language says the following:

“Potential remuneration changes may be requested during the 2011-12 NHANES. In the future, it may be necessary to test methods to encourage more participants to accept weekday MEC appointments, to avoid overly crowded exam sessions. Currently weekend appointments are frequently filled within the first two weeks at an exam site. As more participants are scheduled for exams, the already full weekend exam sessions may become overbooked with participants who are only available on weekends. Overbooking can result in incomplete data due to not having enough time to get all participants through their schedule of exams. Finding incentives to encourage participants to accept a weekday examination will ease the strain on the weekend sessions and increase the likelihood of having complete data on everyone who is MEC examined.

“If NCHS is unsuccessful in shifting more appointments to weekdays we may return to OMB with a change request for differential remuneration based on the day of the week. That is, offering higher remuneration for weekday MEC visits than for weekend appointments to make a weekday appointment more attractive to participants with schedules flexible enough to attend either a weekend or weekday MEC session.”

There is also historical experience to support this request. In NHANES III (1988-94) differential remuneration was successfully used to get participants to come to the examination session (morning, afternoon, or evening session) they were randomly assigned to. In prior NHANES, data were lost due to failure of the participants to attend the randomly assigned session.

Only a request to modify NYFS remuneration is being made. We are not requesting a change to any other aspect of the survey. Burden, interview questions, examination protocols, etc. remain the same.

12. Estimates of Annualized Burden Hours and Cost.

The HPV Prevalence Among U.S. Men Pilot Study has been budgeted for 10 minutes. The first 5 minutes are allocated to counseling by the MEC physician and the remaining 5 minutes are for the actual collection. We will test for approximately four weeks, at one NHANES location. The maximum number of respondents would be 200 (ages 14-59) and the maximum burden 33 hours (200 respondents \*10/60 hour = 33 hours).

The NHANES Dental Fluorosis Imaging Project Feasibility Study has been budgeted for 5 minutes. We will test for approximately eight weeks, at two NHANES locations. The maximum number of respondents would be 155 (ages 6-19) and the maximum burden 13 hours (155 respondents\*5/60 hour = 13 hours).

The total burden is 46 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. NHANES HPV Prevalence Among U.S. Men Pilot Study
- B. NHANES Dental Fluorosis Imaging Project Feasibility Study