

National Health and Nutrition Examination Survey

OMB No. 0920-0950

(Expires November 30, 2015)

**Nonsubstantive Change to conduct Oral HPV Self-collection Follow-up
Feasibility Study**

Contact Information

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This is a request for a nonsubstantive change to the National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0950, exp. November 30, 2016), conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), to conduct pilot/ methodological studies. The proposed changes would not alter the currently approved burden hours.

The following feasibility study is planned:

NHANES Oral Human Papilloma Virus (HPV) Self-Collection Follow-up, Ages 18-69 years
An HPV oral rinse specimen is currently collected in the mobile examination center (MEC) for both youth and adults 14-69 years. A self-collection oral rinse specimen collection and short questionnaire, six months following the baseline MEC collection, is proposed for just adult NHANES participants (age 18-69). The maximum number of participants is 225.

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 2nd 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 the feasibility study are detailed below. The study will begin as soon as clearance is received.

An oral rinse HPV collection now takes place during the dental examination in the mobile examination center. This study will determine if it is feasible for respondents to perform a similar collection by themselves at home, and answer a short questionnaire, 6 months later. The aims of the feasibility study are: 1) to investigate the rates of successful re-contact and follow-up participation (self-collection and questionnaire); and 2) to evaluate the quality of self-collected oral rinse samples.

Results from the pilot study will be used to assess the protocol for inclusion of a longitudinal follow-up on the natural history of oral HPV, beginning in the NHANES main study in 2016 or 2017. Consequently, the main study may include self-collection of oral specimens at 6, 12, 18, and 24 months, from baseline. Any proposed changes to the NHANES main study will be submitted to OMB for review and approval before such changes are implemented.

3. Explanation of any payment or gift to respondents.

Participants in the Oral HPV Follow-up feasibility study will be remunerated \$50. This remuneration was approved as part of the 2014 NHANES Revision package (OMB No. 0920-0950), and is for the return of both the self-collection specimen, and for responding to the questionnaire. This level of remuneration being requested is considered important to response rates, especially in light of the fact that there will be six months between the time the respondent completed their MEC exam and the point of re-contact for this follow-up activity. Here is how this amount of remuneration compares to levels approved for existing or past follow-up activities.

- **Dietary Phone Follow-up:** three to ten days after the MEC exam via a phone call; remuneration of \$30 for each completed interview.
- **Physical Activity Monitor:** worn for 7 full days beginning the day after the MEC exam; remuneration of \$40 once monitor was mailed back.
- **24 Hour Urine:** soon after the MEC exam on a day chosen by the respondent; \$100 cash incentive per specimen collected
- **Home Urine Collection (HUC):** offered to 24 hour urine participants after they correctly complete at least one of the 24 hour collections; remuneration of \$50 for sending a completed urine sample to the lab.

4. Estimates of Annualized Burden Hours and Cost.

The NHANES Oral HPV Follow-up Collection is budgeted for 10 minutes (See Table 1). Five minutes of this burden is allocated for the participant to answer the questionnaire, and another 5 minutes is allocated for the participant to self-collect the specimen. Participants who participated in the 2015 baseline oral HPV collection will be eligible until a sample of 225 participants has been notified about the follow-up. The maximum number of respondents would be 225 (ages 18-69 years) and the maximum burden 38 hours (225 respondents *10/60 hour = 38 hours).

The burden hours for this feasibility study are captured in the “special studies” line of the currently approved NHANES OMB package. This study does not require any additional burden hours.

TABLE 1 – ANNUALIZED BURDEN HOURS AND COSTS

Type of Respondent	Form	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)	Total Burden Hours
Individuals in households	Oral HPV Follow-up Feasibility Study Adults Form	225	1	10/60	38
Total					38

5. Explanation for Program Changes and Adjustments.

The burden hours for this feasibility study are captured in the “special studies” line of the currently approved NHANES OMB package. This study does not require any additional burden hours.

List of attachments:

- A. NHANES Oral HPV Follow-up