

National Health and Nutrition Examination Survey

OMB No. 0920-0237

(Expires November 30, 2009)

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

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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 a pilot test 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.”

This specific request is to modify the remuneration for a pilot test in the change package that was approved June 18, 2008.

The pilot test is for the post-examination data collection of a urine specimen (ages 6+). There was a clerical error in the original change package related to the remuneration and we have changed one detail of the pilot test during the past 2 months. The remuneration is addressed below in item A.9. The change is described in A.2.a. below. The change increased the Estimates of Annualized Burden Hours and Cost (item 12) from 116 to 350 responses; however, the burden was already approved in the full survey submission.

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 started piloting and developing methods for NHANES 2009-10 in the spring of 2007 and proposes to continue pilot testing in 2008.

2. Purpose and Use of the Information Collection

All pilot tests will include only NHANES participants.

a. Post examination data collection--Urine specimen collection pilot (ages 6+)

Chronic kidney disease (CKD) is a serious condition associated with premature mortality, decreased quality of life, and increased health-care expenditures. Untreated CKD can result in end-stage renal disease and necessitate dialysis or kidney transplantation. Risk factors for CKD include cardiovascular disease, diabetes, hypertension, and obesity. Persistent albuminuria is

used to determine kidney damage for categorizing persons as having stage 1 and stage 2 CKD. Two urine samples are needed to assess persistent albuminuria and confirm the presence of kidney damage.

Further discussions between NCHS and the collaborator led us to decide to collect an additional urine specimen on all participants 6 and older. Previously it had been planned to include participants with microalbuminuria plus 5% of those without microalbuminuria. The primary reason for this change was because the method we are using for the home collection is more specific in identifying microalbuminuria associated with chronic kidney disease. Therefore, having this result on the full NHANES sample is more valuable than just having a second sample on those with an elevated first sample. This decision allows NHANES to provide the collection kit and instructions to participants while they are at the mobile examination center.

9. Explanation of any payment or gift to respondents.

Participants will be remunerated forty dollars. The remuneration will be mailed to participants after the urine sample is collected at home and the specimen has been received at the laboratory.

In the original request the value of \$20 was listed as the remuneration amount. This was a typographical error that was not caught and consequently was carried through into the change document. Similar post-examination components have been remunerated at least \$40 in the past. The most similar component was the Physical Activity Monitor (PAM) that was part of the NHANES 2003-6 protocol. The monitor was explained and given to the participant at the mobile examination center (MEC) and they were asked to mail it back after wearing it for portions of 7 days. The urine specimen will be explained and the collection and mailing materials will be given to the participant at the MEC. The participant will have to provide a urine sample at a specific time of day (the first time they urinate after finishing their sleep) on specified days of the week (Saturday through Wednesday), carefully package the specimen according to a protocol, and mail it to the laboratory (on the same day it is collected).

In 2002 during the pilot for the PAM DHANES remunerated \$30. The response rate during the pilot test was 67%. We concluded that an increase in remuneration would likely increase the response rate. We remunerated \$40 from 2003-6 and the response rate was 92%. We feel strongly that the \$40 remuneration contributed to that high response rate.

12. Estimates of Annualized Burden Hours and Cost.

Burden category	Number of respondents for four weeks	Number of responses per respondent	Average burden per response (hours)	Total respondent burden (hours)
7. Follow-up and Special Studies				
Second (post examination) Urine Collection	350	1	10/60	58

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Pilot tests of 2009-10 Examination Content Components

The Second Urine Collection pilot has been budgeted for 10 minutes. We will conduct a pilot test at one NHANES survey location. The maximum number of respondents expected would be 350 (ages 6+) and the maximum burden 58 hours (350 respondents*(10/60 hour) = 58 hours).

This time was already budgeted and approved in line 7, 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.