

**National Health and Nutrition Examination Survey**

**OMB No. 0920-0950**

(Expires December 31, 2019)

**Nonsubstantive Change to conduct  
NHANES Developmental Projects**

**Contact Information**

David Woodwell, MPH  
Chief, Planning Branch  
National Health and Nutrition Examination Survey  
National Center for Health Statistics  
Centers for Disease Control and Prevention  
3311 Toledo Road  
Hyattsville, MD 20782

Telephone: 301-458-4327

FAX: 301-458-4028

E-mail: [DWoodwell@cdc.gov](mailto:DWoodwell@cdc.gov)

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This is a request for nonsubstantive changes to the National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0950, Exp. Date 12/31/2019), conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). The currently approved package includes a proposal to conduct developmental (including administrative) projects to support NHANES data collection. This submission includes a request to add one new administrative self-tracker appointment tool, update seven consent forms based on requests from the NCHS Ethics Review Board (ERB), add a new factsheet and to make one update to the list of laboratory measures. All changes are minor in nature and do not involve changes in burden to participants.

#### Proposed Administrative Activities

- Add a “Make a Plan” Tracker Tool
- Update selected recruitment/consent materials requested by the NCHS ERB
- Update the Laboratory Analyte List
- Add an “Why is it Important for 3-5 Year Olds to Provide Urine in NHANES” Fact Sheet

#### A. Justification

##### 1. Circumstances Making the Collection of Information Necessary.

NHANES is conducted annually. It includes a household interview, performed in participants’ homes and physical measures and additional interviews performed in the NHANES Mobile Examination Center (MEC). There may also be follow-up interviews or components (such as a second dietary interview) 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 by changing/modifying survey content. Though collected annually, NHANES data are released in two-year cycles. Periodically, it may be necessary to update administrative forms or procedures for the survey.

##### 2. Purpose and Use of the Information Collection

The purpose and use of each proposed project are detailed below. Projects will include NHANES participants. Participation is voluntary. Projects would be implemented as soon as feasible after clearance has been received.

#### “Make a Plan” Tracker Tool

NHANES is experiencing a growing trend of missed appointments and noncompliance on the part of the survey participant. Because a sufficient number of examined participants are required for adequate analyses of NHANES data, we have designed a tracker tool to help participants remember their interview and examination appointments, and to provide them with contact information in case they need to reschedule their appointment. This tracker tool is not used to collect any information or data from participants. This is a reminder card, which the SP can choose to keep or not. It provides information that may make NHANES participation easier for them, therefore helping to reduce their burden.

The tool consists of a post-card sized document outlining the steps between eligibility and the completion of the mobile unit examination. It will be given to the participant at their home once they are identified as eligible for the survey. If there are multiple members in the family participating in NHANES, each member will get their own tracker. Interviewers will use pens with different colors of ink to help distinguish the trackers. The field interviewer will review the participation steps on the tracker tool, placing a magnet/sticker on each block as he/she describes how the participant will track their completed steps. The goal is to help participants keep their appointments. Please see Attachments 1a and 1b for the prototypes of the tracker tool. The more colorful version (Attachment 1a) was designed with children in mind, but could be used with any participant.

#### Updated Recruitment/Consent Documentation

The NCHS Ethics Review Board (ERB), the Institutional Review Board (IRB) of record for NCHS, recently asked for small changes to several NHANES recruitment/consent documents. The revised documents are in Attachments 2a-2g. A list summarizing what these changes are is in Attachment 2h. These revised documents do not represent any change in burden for survey participants.

NHANES also developed a letter, as an additional field interviewer tool, to address respondents' concerns regarding immigration status privacy. This new letter is in Attachment 2i.

#### Updated Laboratory Analyte List

NHANES is already approved to assess fat-soluble vitamins and micronutrients, such as Vitamins A, E and carotenoids in serum. The list of specific fat-soluble micronutrients is being updated to include *delta*-Tocopherol. This does not represent any change in burden for survey participants. This additional carotenoid will be assessed from the same blood sample used to measure the other carotenoids already being collected in NHANES. Please see Attachment 3 for the updated fat-soluble vitamins and micronutrients table.

#### 3-5 Year Olds Urine Fact Sheet

NHANES collects urine from 3-5 years old participants. Because these participants are young, it is common for their parents/guardians to help with the urine collection. We are adding a fact sheet that explains to parents/guardians why it is important for 3-5 year olds to provide this urine sample. The addition of this document does not represent a change in burden for survey participants. Please see Attachment 4 for the factsheet. (While the wording will remain the same, it is possible that different pictures will be used with subsequent fact sheets.)

#### 9. Explanation of any payment or gift to respondents.

Participants will not receive any additional incentives because of these administrative changes. They will simply receive the already approved incentives given to regular NHANES participants.

## 12. Estimates of Annualized Burden Hours and Cost

The administrative changes described in this clearance request do not represent a change in burden for survey participants. Interviewers already explain the process of making a NHANES MEC appointment and traveling to the exam to participants verbally. The “Make a Plan” Tracking Tool is simply a printed handout summarizing the same information. The goal is for participants to put the tool in a place they can see, such as on a refrigerator door or bulletin board, to serve as a reminder to keep their appointment.

Neither the edits to the consent forms, the additional laboratory analyte nor the factsheet represent an increase or decrease in burden to survey participants.

## 15. Explanation for Program Changes and Adjustments.

The projects described in this submission do not change the 79,894 burden hours in the currently approved clearance. They are all administrative changes that do not affect the time participants spend taking part in NHANES.

### List of attachments:

- 1a. Tracker Tool – multi color
- 1b. Tracker Tool
- 2a. 2018 Advance Letter
- 2b. Authorization for Transportation Arrangements
- 2c. 2018 Future Research non DNA Consent
- 2d. 2018 Home Interview Consent
- 2e. 2018 NHANES Health Measurements
- 2f. NHANES Child Assent Brochure - inside
- 2g. MEC Adult Parental Consent Brochure
- 2h. Summary of ERB requested changes to text in participant materials
- 2i. Confidentiality and Immigration Status letter
3. Laboratory Assessments Update 2018
4. 3-5 Year Olds Urine Fact Sheet