National Health and Nutrition Examination Survey
OMB No. 0920-0950
(Expires December 31, 2019)

Nonsubstantive Change to conduct
NHANES Developmental Projects

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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 studies to support NHANES data collection. This submission includes a request to initiate 4 such studies. One study involves minor changes to the consent process, which is not included in the burden estimate. Three studies are described in the burden table for this change request. The burden hours for these projects have already been approved. Findings from these studies will be reported to OMB and uploaded to Reginfo.gov.

Proposed Pilot Studies

- Balance/ vestibular/visual function test
- Blood Collection – Infants less than 12 months old
- Electronic Consents (e-consent) - Phase II
- Words-In-Noise Test

A. Justification

Circumstances Making the Collection of Information Necessary.

NHANES is conducted annually. It includes a household interview, done in participants' homes and physical measures and additional interviews done in the NHANES MECs. There may also be follow-up interviews or components (such as a 2nd 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. Some survey content stays the same across multiple cycles of NHANES. But new survey content may be added, existing content may be modified or some content may be dropped at the beginning of each two-year survey cycle.

There is great value in testing new methodologies before they are implemented in the main survey. Testing allows NHANES staff to determine how long the protocol will take and 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 without affecting the results from the main study. Finally, 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 the actual survey. Since data collection is continuous, methodology studies must be conducted during ongoing NHANES data collection. This nonsubstantive change request captures 4 such methodological studies, the burden hours for which have already been approved on line 5 (Developmental Projects & Special Studies) of the burden table within the current package (OMB No. 0920-0950, Exp. Date 12/31/19).

1. Purpose and Use of the Information Collection

The purposes and uses of each proposed study are detailed below. Projects will include NHANES 2017-18 participants. Participation is voluntary. Testing would take place across multiple NHANES locations, as needed to achieve the desired sample sizes. Projects would be conducted as soon as feasible after clearance has been received.

Balance/ vestibular/visual function

Balance disorders are very common in the United States, especially in older persons.[1] NHANES data from 1999-2004 indicated that ~30% of US adults 40 years and older have some balance dysfunction. It increases to 70% in adults 70-79 years old and 85% in adults 80+ years old. [2]This pilot study will examine three clinical measures of balance assessment and determine if they can be conducted in NHANES. One measure, the Modified Romberg Test (MRT) for balance, has been conducted in past NHANES, but a modification has been made which requires pilot testing. The other measures are Dynamic Visual Acuity (DVA), and Contrast Sensitivity Testing(CVT) which would be new for NHANES. The MRT will estimate the prevalence of balance disorders; the DVA will determine the percent of balance disorders related to inner ear problems; and CST will indicate if the balance disorder is related to vision dysfunction.

People with balance problems have a six fold increased risk of falling.[3] In 2014, falls were the leading cause of fatal and non-fatal injuries in adults 65+. Among adults 65+, 3 million sought emergency department treatment; 800,000 were hospitalized; and 27,000 died in 2014. It is important to determine if these conditions are becoming more common and to characterize more completely, what is causing these balance disorders.

This proposal is to pilot test the Balance/ vestibular/visual function component.[4] Up to 250 NHANES participants 40 years and older, who attend their scheduled NHANES visit to the MEC, will be asked to have these tests. The amount of time needed for this project is estimated at 22 minutes per participant (10 minutes to test balance, 5 minutes for vestibular function and 7 minutes for contrast sensitivity).

The revised Modified Romberg Standing Balance Test[5] has been specifically designed to maintain compatibility with the earlier balance data collected in NHANES 1999–2004 and add a

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[1] NIDCD (1995). National Strategic Plan: Balance and Balance Disorders. National Institute on Deafness and Other Communication Disorders, National Institutes of Health, NIH Publication No. 96-3217, Bethesda, Maryland.

[2] Agrawal Y, Carey JP, Della Santina CC, Schubert MC, Minor L (2009). Disorders of balance and vestibular function in US adults: Data from the National Health and Nutrition Examination Survey, 2001-2004. *Arch Intern Med*, 2009 25;169(10):938-44.

[3] Bergen G, Stevens MR, Burns ER (2016). Falls and fall injuries among adults aged ≥65 years — United States, 2014. *MMWR*, 65(37);993–998.

[4] Gershon RC, Cella D, Fox NA, Havlik RJ, Hendrie HC, Wagster MV (2010). Assessment of neurological and behavioural function: The NIH Toolbox. Lancet Neurol, ;9(2):138-9.

[5] Rogers JH (1980). Romberg and his test. J Laryngol Otol, 94(12):1401-4.

new test element. Participants will stand in a fixed position under conditions of increasing difficulty (firm surface, foam surface, eyes open, eyes closed, head still, head moving) to evaluate their ability to maintain balance using various systemic inputs to balance. An accelerometer will be tested to measure amount of swaying. The Dynamic Visual Acuity Test[6,7,8] is new to NHANES. Participants will take a brief visual acuity test with their head still by identifying "optotypes" presented on a computer screen at varying sizes (similar to standard vision test); participants will then repeat the test as the examiner moves their head from side to side to evaluate vestibulo-ocular reflex function. The difference in visual acuity when the head is moving versus not moving is an indicator of the inner ear problems for balance. Contrast sensitivity testing will evaluate an individual's ability to detect low contrast images. Research has shown that visual impairment is related to balance dysfunction.[9]

The objectives of this pilot project can be summarized as follows:

- Assess the viability of conducting the proposed protocols in the NHANES Mobile Exam Center (MEC) environment
- Test the equipment needed to conduct these exams
- Assess/track the rate of participation

If this pilot is successful and these tests are included in full NHANES, this will allow NCHS to:

- Assess current percent of the US population with balance disorders, and to see if this percent has changed since 1999-2004
- Measure the percent balance disorders that can attributed to inner ear dysfunction or visual dysfunction.
- Evaluate the current risk factors of balance disorders and determine if they have changes since 1999-2004

These components were proposed by researchers from the Epidemiology and Statistics program, National Institute on Deafness and Other Communication Disorders (NIDCD), part of the National Institutes of Health (NIH). More details about the Balance/ vestibular/Visual function Pilot Study are provided in Attachments 1a and 1b.

<u>Blood Collection – Infants < 1 year old</u>

The relationship of early child nutrition to health outcomes throughout the lifespan has grown as an important public health interest. From birth to 12 months (0-12 mo) is a critical life stage

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[6] Bermúdez Rey MC, Clark TK, Wang W, Leeder T, Bian Y, Merfeld DM (2016). Vestibular perceptual thresholds increase above the age of 40. Front Neurol, 7:162. DOI: 10.3389/fneur.2016.00162.

[7] Rine RM, Schubert MC, Whitney SL, Roberts D, Redfern MS, Musolino MC, Roche JL, Steed DP, Corbin B, Lin CC, Marchetti GF, Beaumont J, Carey JP, Shepard NP, Jacobson GP, Wrisley DM, Hoffman HJ, Furman G, Slotkin J (2013). Vestibular function assessment using the NIH Toolbox. Neurology, 12;80(11 Suppl 3):S25-31

[8] Riska KM, Hall CD (2016). Reliability and normative data for the Dynamic Visual Acuity test for vestibular screening. Otol & Neurotol, 37(5):545-552.

[9] Willis JR, Vitale SE, Agrawal Y, Ramulu PY. Visual impairment, uncorrected refractive error, and objectively measured balance in the United States. JAMA Ophthalmol. 2013;131(8):1049-1056.

nutritionally because of the increased demand for nutrients to support growth and development. Early child nutrition impacts taste preferences, dietary behaviors, and the development of dietary patterns. Inadequate intake of nutrients, poor diet behaviors, and unhealthy weight gain in early childhood lead to numerous developmental and long-term health problems. Traditionally, the Dietary Guidelines for Americans has focused on individuals ages 2 years and older. The Agricultural Act of 2014 has mandated that beginning with the 2020-2025 edition, the Dietary Guidelines includes comprehensive dietary recommendations for children from birth to 24 months (0-24 mo). As a result, nationally representative data on children 0-24 mo are crucial to advancing the science base used to inform current and future Federal nutrition and related health programs, policies, and consumer information. Currently, NHANES collects and analyses blood from children 1 year of age and older. Thus, no data are currently available on the blood levels of relevant analytes for infants (0-12 mo). This proposal addresses the opportunity for a pilot study to lay the foundation for moving towards regularly collecting blood from infants in NHANES.

NHANES currently collects blood from participants ages 1 year and older. This proposal is to pilot test obtaining blood collection from infants less than 1 year old. The proxy (parents /guardians etc.) of up to 100 NHANES participants, from birth to less than 12 months, would be asked to consent to their infants' blood being drawn via heel stick (0 to 6 months) or finger stick (6 months to less than 12 months). The amount of time needed for this project is estimated at 8 minutes per participant.

The objectives of this project can be summarized as follows:

- Obtain blood collection via heel sticks for participants 0-6 months old
- Obtain blood collection via finger stick for those 6 months to less than 12 months
- Assess how much blood can be obtained
- Assess/track the rate of participation
- From the blood collection, obtain the following 5 top priority measures
    - Ferritin and soluble transferrin receptor (sTfR)
    - C-reactive protein (CRP) and alpha-1-acid glycoprotein (AGP)
    - Retinol Binding Protein (RBP)
    - Hemoglobin (Hb)
    - Folate
- If adequate blood volume is available, obtain the following additional measure
    - Metals panel for Lead (Pb)
    - Metals panel for total mercury (for estimating methylmercury, MeHg)
    - Per-and polyfluoroalkyl substances (PFASs) panel

This component was proposed by a collaborative effort among the following agencies:

- CNPP Center for Nutrition Policy and Promotion, USDA
- EPA Office of Water, Standards and Health Protection Division, Environmental Protection Agency
- ERS Economic Research Service, USDA
- FNS Food and Nutrition Service, USDA
- NCBDDD National Center on Birth Defects and Developmental Disabilities, CDC, HHS
- NCCDPHP National Center for Chronic Disease Prevention and Health

Promotion, CDC, HHS
- NCI National Cancer Institute, NIH, HHS
- NHLBI National Heart, Lung, and Blood Institute, NIH, HHS
- NICHD National Institute of Child Health and Human Development, NIH, HHS
- ODPHP Office of Disease Prevention and Health Promotion, OASH, HHS
- ODS Office of Dietary Supplements, NIH, HHS

More details about blood collection in infants less than 12 months old are provided in Attachment 2a and 2b.

Electronic Digital Signature to Document Consent - Phase II

NHANES would like to expand the use of an electronic signature process (e-consent) for consent that allows a participant to sign via an electronic screen vs. a hard copy piece of paper. The current e-consent process covers forms related to the household interview. We would like to expand their use to cover forms related to the Mobile Exam Center (MEC) exam. There are no changes to the consent protocol currently in place, except for the following:

- The signature will be captured electronically.
- The current description for age "under 16" on the Authorization for Transportation form will be changed to "birth to 15 years old". (See Attachment 3e for the original form with proposed changes noted and Attachment 3l for the revised form.)
- The current description for age "under 18" on the Authorization for Transportation form will be changed to "birth to 17". (See Attachment 3e for the original form with proposed changes noted and Attachment 3l for the revised form.)

The proposed electronic signature option is burden-neutral to participants, but a benefit overall in terms of (a) participant preferences and (b) managing paperwork in the MEC. The e-consent process would be offered to all participants who currently sign hard copy MEC consents/assents. A blank hard copy of the consent form(s) will also be left with each respondent. If the respondent requests a printed signed copy of the form with all of the information captured electronically, this would be provided.

For Phase II, we want the following consents to have signatures captured electronically when the interviewers schedule the MEC appointments:

- Consent/Assent and Parental Permission for Examination at the MEC (Attachment 3b hard copy and 3k e-consent)
- Child Assent (SPs 7-11) for the Examination at the MEC (Attachment 3c hard copy and 3i e-consent)
- Child Assent (SPs 12-17) for the Examination at the MEC (Attachment 3b hard copy and 3j e-consent)
- Consent/Assent and Parental Permission for Specimen Storage and Continuing Studies (Attachment 3d hard copy and 3k e-consent)
- Authorization for Transportation Arrangements for Persons under 18 Years of Age (Attachment 3e hard copy and 3i,3j,)

Goals

- Streamline the consent process for participants
- Improve time management for field interviewers (FI) by transitioning from a manual consent process to an automated and electronic process. This may allow interviews to focus more of their time of efforts to recruitment, non-response related efforts etc.
- Increase efficiency and accuracy of form completion by
    - Presenting only the required consent/assent form screens, participation statement screens, and signature screens that are appropriate for the sampled person's (SP) age and emancipation status, and
    - Allowing the program to take the respondent's tablet entries and fill the appropriate boxes and signature lines on hard copy forms.
- Improve time management for field office staff by minimizing time spent reviewing hardcopy forms for accuracy, scanning forms for documentation, and shipping forms for storage. This may allow field office to focus more of their time of efforts on activities such as refusal conversions and other non-response related efforts etc.

More details about Electronic Digital Signature to Document Consent (PHASE II), including copies of the existing hard copy consent forms, as well as proposed screenshots for the e-consent process, are provided in Attachments 3a-3f.

Words-In-Noise

Good hearing ability is an essential aspect of normal communication and plays an important role in safety and awareness in nearly every part of daily life. Hearing loss is a widespread problem, affecting nearly 40 million people in the US alone. More people have hearing loss impairment than any other disability. Although the pure-tone audiogram remains the gold-standard test of hearing ability, many individuals report some levels of hearing trouble although they have no measurable hearing impairment based on the pure-tone audiometry.

Recognizing speech in the presence of background noise challenges the auditory system and has been used for years as a method of distinguishing between hearing losses that involve only "acuity" and those which involve "clarity." Words-in-noise (WIN) has been proposed as a sensitive measure of synaptopathic damage[10]. Words-in-Noise, is a test to assess the ability of understanding spoken words with background noise. This then yields an ecologically valid measure of hearing because a substantial portion of communication in the real world occurs in less than ideal environments. The Words-in-Noise test has been extensively tested[11] and validated in various populations[12], including an older population[13]. The test has been recommended as part of the NIH Toolbox[14], making it freely available to researchers. Words-in-

[10] Liberman MC, Epstein MJ, Cleveland SS, Wang H, <aison SF (2016). Towards a Differential Diagnosis of hidden Loss in Humans. Plos One, 11(9):e0162726.
[11] Wilson RH, McArdle R (2007). Intra- and inter-session test, retest reliability of the Words-in-Noise (WIN) test. J Am Acad Audiol, 18:813-825.
[12] Zecker SG, Hoffman HJ, Frisina R, Dubno JR, Dhar S, Wallhagen M, Kraus N, Griffith JW, Walton JP, Eddins DA, Newman C, Victorson D, Warrier CM, Wilson RH (2013). Audition assessment using the NIH Toolbox. Neurology, 80(11 Suppl 3):S45-8.
[13] Wilson RH (2011). Clinical experience with the Words-in-Noise test on 3430 veterans: Comparisons with pure tone thresholds and word recognition in quiet. J Am Acad Audiol, 22:405-423.
[14] https://www.youtube.com/watch?

noise testing is non-invasive and easy to administer, making it suitable for NHANES.

This proposal it to conduct a Words-in-Noise pilot test among adults aged 70 years and older. Up to 250 NHANES participants in this age range, who attend their scheduled NHANES visit to the MEC, will be asked to have this test. During the test, the SP will be asked to repeat a list of 35 words presented in a background of multi-talker babble in headphones. The amount of time needed for this project is estimated at 5 minutes per participant.

The objectives of this project can be summarized as follows:

- To determine the operational feasibility of collecting WIN test exam data according the WIN test exam protocols in the existing NHANES audiometry environment.
- To determine the complete rate of WIN test among the eligible participants.

This component was proposed by researchers from the Epidemiology and Statistics program, NIDCD/NIH. More details about the Words-in-Noise pilot study may be found in Attachments 4a and 4b.

9. Explanation of any payment or gift to respondents.

Participants in the pilot studies described in this non-substantive clearance request will not receive any additional incentives. They will simply receive the already approved incentives given to regular NHANES participants.

12. Estimates of Annualized Burden Hours and Cost

The Balance/ Vestibular/Visual Function Pilot Study is budgeted for 22 minutes. The maximum number of respondents would be 250 adults. The maximum burden is 92 hours (250 respondents*22/60 hours = 92 hours).

The Blood Collection – Infants Pilot Study is budgeted for 8 minutes. The maximum number of respondents would be 100 infants. The maximum burden is 13 hours (100 respondents*8/60 hours = 13 hours).

The Words-in-Noise Pilot Study is budgeted for 5 minutes. The maximum number of respondents would be 250 and the maximum burden 21 hours (250 respondents*5/60 hour = 21 hours).

The total burden for all projects combined is 126 hours. This time was already budgeted and approved in line 5 (“Developmental Studies & Special Projects) of the original submission. No additional burden is sought.

TABLE 3 – ANNUALIZED BURDEN HOURS AND COSTS

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Type of Respondent	Form	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)	Total Burden Hours
Balance/Vestibular Function Pilot Study Participants	Balance/Vestibular/ Vision Function Pilot Study Form	250	1	22/60	92
Blood Collection – Infants Pilot Study Participants	Blood Collection – Infants Pilot Study Form	100	1	8/60	13
Words-in-Noise Pilot Study Participants	Words-in-Noise Pilot Study Form	250	1	5/60	21
Total					126

15. Explanation for Program Changes and Adjustments. The five projects described in this submission do not change the burden hours from the previously approved clearance. The burden hours in this submission are captured in the "Developmental Studies & Special Projects" line of the burden table currently approved for NHANES.

List of attachments:
1a. Balance/Vestibular/Visual Function Description
1b. Balance/Vestibular/Visual Form
2a. Blood Collection – Infants Description
2b. Blood Collection – Infants Form
3a. E-Consent II Description
3b. E-Consent II Adult Consent HC
3c. E-Consent II Child Assent HC
3d. E-Consent II Future Research HC
3e. E-Consent II Transport Auth HC
3f. E-Consent II Child_Brochure
3g. E-Consent II Adult Brochure_Cover HC
3h. E-Consent II Adult_Brochure_Inside HC
3i. E-Consent II Assent 7-11
3j. E-Consent II Assent 12-17
3k. E-Consent II Consent Adult
3l. Revised E-Consent II Transport Auth HC
4a. Words-in-Noise Description
4b. Words-in-Noise Form