

Supporting Statement B for Request for Clearance
National Health and Nutrition Examination Survey

OMB No. 0920-0950

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Table of Contents

B. Collections of Information Employing Statistical Methods.....	3
1. Respondent Universe and Sampling Methods.....	3
2. Procedures for the Collection of Information.....	4
3. Methods to Maximize Response Rates and Deal with Nonresponse	8
4. Tests of Procedures or Methods to be Undertaken.....	10
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data.....	12

Attachment List

Attachment 1 – Applicable Laws or Regulations (Excerpts)
Attachment 2a – 60-Day Federal Register Notice
Attachment 2b – Public Comments to the 60-day Federal Register Notice
Attachment 3a – Summary of 2019-2020 Questionnaire Changes
Attachment 3b – Screener
Attachment 3c- Screener Hand Cards
Attachment 3d – Household Interview
Attachment 3e-Household Interview Hand Cards
Attachment 3f – Mobile Exam Center (MEC) Interview and Examination
Attachment 3g- MEC Computer Assisted Personal Interview (CAPI) & Dietary Recall (DRQ)
Hand Cards
Attachment 3h` - Telephone Dietary Recall and Dietary Supplements
Attachment 3i – Flexible Consumer Behavior Survey (FCBS) Description
Attachment 3j– FCBS Phone Follow-Up
Attachment 3k – FCBS Hand Cards
Attachment 3l – Questionnaires & Data Collection Forms 2017-2018
Attachment 4 – Developmental Project Reports
Attachment 5a - Laboratory Assessments 2019-2020 and earlier
Attachment 5b - Laboratory Assessments 2017-18 and earlier
Attachment 6 - Agencies consulted 2019-2020
Attachment 7 – NHANES History
Attachment 8a – Letters and Scripts
Attachment 8b - 2018 Advance Letter
Attachment 9a - Consent Forms
Attachment 9b - Consent Brochure
Attachment 9c - Assent Brochure
Attachment 9d - Consents FAQ
Attachment 9e - assent 7-11
Attachment 9f - assent 12-17
Attachment 9g - e-consent Adult
Attachment 9h - Rev Transport Auth HC 17-18
Attachment 9i - NHANES Health Measurements
Attachment 9j - 2018 Auth for Transport
Attachment 9k - Confidentiality Brochure
Attachment 9l - Future Research non DNA English
Attachment 9m - Home Intv Consent English Final
Attachment 9n - NHANES Health Measurements

Attachment 9o - Child_Assent_Brochure_inside
Attachment 9p - MEC_Adult_ParentalConsentBrochure
Attachment 10 – Ethics Review Board (ERB) Approval
Attachment 11 – Human Papillomavirus Informational Flyer
Attachment 12 – Developmental Projects & Special Studies Testing
Attachment 13 – 24 hour BP pilot
Attachment 14a – Sample Design Tables 2019-2020
Attachment 14b – Sample Design 2015-2018
Attachment 15 - 3-5 Yr Urine Fact Sheet
Attachment 16 - Report of Findings
Attachment 17a – Example Background Materials
Attachment 17b – Example Background Materials
Attachment 18a- Make a Plan - multi color
Attachment 18b- Make a Plan tracker
Attachment 19a- NHANES Incentive Pilot Summary
Attachment 19b- NHANES Incentive Pilot Details
Attachment 20a DXA Crossover Study Description
Attachment 20b DXA Crossover Study Form

Supporting Statement B

National Center for Health Statistics (NCHS) National Health and Nutrition Examination Survey (NHANES)

B. Collection of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

Overview of the Continuous NHANES Sample Design

The NHANES sample design is based on a continuous on-going annual survey of the non-institutionalized, civilian population of the United States. From 1999 through 2018, each single year and any combination of consecutive years comprises a nationally representative sample of the U.S. population. The primary objective of NHANES is to estimate a broad range of descriptive health and nutrition statistics for sex, race/Hispanic origin, age and income subdomains of the U.S. population. Data are publicly released every two years to improve the analytic stability of estimates and to decrease disclosure risk. From 1999-2018 several subgroups are oversampled to ensure adequate sample sizes for selected population subgroups. Those groups are African Americans, Hispanics, Asian Americans, older persons, and low-income whites.

As with previous NHANES surveys, the design for the current NHANES is a stratified, multistage area probability sample of the civilian non-institutionalized population of the U.S. In hierarchical order, the stages of the sample selection are first: selection of Primary Sampling Units or PSUs (counties or small groups of contiguous counties); second: segments within PSU (a block or group of blocks containing a cluster of households); third: households within segments; and fourth: one or more survey participants within households. The assumption is that the field operations will include two mobile examination center (MEC) teams in operation and approximately 5,000 persons examined in 15 PSUs per year. The expected sample size is based on past NHANES experience with response rates for each subdomain of interest.

Background on the Sample Design for NHANES 2019-2022

Since 2007, statisticians have selected a four-year sample for NHANES with each year being a nationally representative sample. Previous four-year designs were NHANES 2007-2010¹, NHANES 2011-14², and NHANES 2015-18 (See Attachment 14b). The sample design selected for NHANES 2019-2022 is similar to the NHANES 2015-2018 with one exception. The same subgroups will be oversampled: African Americans, Hispanics, Asian Americans, older persons, and low-income whites. However, to increase operational efficiency, the new design will produce a nationally representative sample over the course of a two-year cycle instead of annually. See Attachment 14a for the 2019-20 sample design tables. Because of declining response rates, it has become difficult to reach the target number of examinations (5,000/year) with the current design. Changing to a two-year cycle will permit more days of field work and a greater number of MEC appointments in each PSU which will result in more time to screen and recruit potential participants, and allow for more exam slots.

NHANES 2019-2020 Sample

The NHANES will collect data on a two-year nationally representative sample during 2019-2020, and this submission is limited to seeking approval for the NHANES 2019-2020 sample. The program needs to be flexible in an era of budget uncertainty and plans to evaluate options for NHANES 2021-22. Should funding fall short, the NHANES program may choose to stop oversampling in 2021-22, and draw a new sample. In any case, the program will submit a future change request to seek approval for the NHANES 2021-22 sample design.

References

1. https://www.cdc.gov/nchs/data/series/sr_02/sr02_160.pdf
2. https://www.cdc.gov/nchs/data/series/sr_02/sr02_162.pdf

2. Procedures for the Collection of Information

Data Collection Procedures

A contractor is responsible for data collection procedures. The responsibilities of the contractor are to:

- select Primary Sampling Units (PSUs) and other units of the sample design
- list all dwelling units within each segment
- make advance arrangements for each location
- provide input on NCHS's publicity/outreach methods and materials
- hire and train field staff
- set up and maintain field activities
- set up and maintain the MECs
- translate all questionnaires into Spanish and use translators for other languages, when needed
- create manuals and training programs for all field procedures (including training in NCHS confidentiality guidelines and regulations)
- list the households to be sampled
- select the sample civilian non-institutional U.S. population
- conduct screening and extended interviews in the households
- perform all interview and examination procedures in the examination centers
- design and carry out quality control procedures, and transmit survey data to NCHS.

After the listing procedure (driving each street in the segment to list all dwelling units), which identifies households to be potentially included in NHANES, advance letters are sent to each sampled address informing the occupant(s) that they may be visited by an interviewer. When the interviewer arrives at the home, he or she shows official identification and briefly explains the purpose of the survey. If the person answering the screener questions has not seen the advance letter, a copy is given to him/her. The interviewer then administers the Household Screener Questionnaire Module to determine eligibility. If one or more household members screen in, the interviewer explains the household questionnaires to participants who are at least 16 years old and informs them of their rights and of the confidentiality protection provided (the same information as appears in the Advance Letter, in case they haven't seen it). For persons under 16 who are eligible, the household questionnaire interview is conducted with a proxy, usually the parent or guardian of the survey participant. If there is no one living in the household who is over 16, the teenage participant can be interviewed him/herself. If

emancipated minors are prohibited by state law to participate in research they will be sampled, but not asked to participate and therefore are non-responders. If convenient for the participant, the household questionnaire is administered at first contact. Otherwise, an appointment is made to return to conduct the household interviews. After informing the potential respondent about the interview(s), the respondent is asked to read and sign the Interview Informed Consent Form agreeing to participate in the household interview portion of the survey. For participants who are 7-17 years of age, a parent or guardian consents and the child assents. Consents, Assents and related document are in Attachments 9a-9p).

(Note regarding informed consent for those unable to read the consent form. If the interviewer discovers the participant to be illiterate or visually impaired, etc., the interviewer reads the entire document to the person in front of a witness. The interviewer answers all questions and if the person agrees, s/he signs the form and completes the interview. If the respondent is unable to sign the form, a witness signature is obtained to indicate that informed consent was received on the part of the participant. The same protocol exists for all consent documents.)

The 2019-20 household screener and interview questions appear in Attachments 3b and 3d, respectively. Screener Hand Cards are in Attachment 3c. Household interview hand cards are in Attachment 3e. The Sample Participant and Family Questionnaires are recorded for quality control purposes. Verbal consent is obtained and recorded at the beginning of the questionnaire.

When the questionnaire is completed, the interviewer reviews with the participant the examination informed consent brochure (Attachments 9b and 9c), which contains detailed information about the examination, the next step in NHANES participation. Each person selected in the household is asked to make an appointment for the examination at the MEC. Those who agree to participate are asked to read and sign consent forms for the examination and the storage of specimens. The interviewer then telephones the field staff to make the examination appointments. The interviewer informs the participants that they will receive an incentive for participating in the examination, as well as help with out of pocket expenses such as transportation and childcare, if necessary. If the participant has questions or cannot come at the randomly assigned time the interviewer will provide additional information. As part of explaining incentives the interviewer will inform the participant that they will receive the incentive if they come to the examination. Additionally, the interviewer may mention that participation in components occurring after the examination (2nd dietary recall by phone) may also result in an incentive.

When participants arrive at the MEC, the Coordinator (receptionist) greets them and verifies their identity. Next, we ask the participant to change into a disposable set of exam clothes and slippers. At this point, we also give the participant a container to provide a urine specimen while they are changing into their exam clothes. In addition to the Coordinator, the survey team at each MEC consists of a physician, dietary interviewers, certified medical technologists, health technicians (at least two of whom are radiological technicians), a certified phlebotomist, MEC interviewers, a dentist and a facility equipment specialist.

The 2019-20 MEC questionnaire and examination data collection forms are in Attachment 3f. The corresponding hand cards are in Attachment 3g. Some of the medical findings of the examination are given to the examinees before they leave the MEC. The remaining examination results are mailed to participants at a later date (usually between 6-12 weeks after their MEC exam took place). The sexually transmitted disease (STD) laboratory test results are not mailed with the other exam results, but rather reported to participants only via telephone to

further protect their confidentiality. The participants call NCHS for the results and provide the personalized password they created during their MEC examination. Examples of the Reports of Findings given to examinees and a description of the Reports of Findings process are included in Attachment 16.

At any given time during the calendar year, examinations are conducted at two survey locations simultaneously. This means the field staff and household interviewing staff support two complete examination teams at the same time for the eleven months of the year NHANES is in operation. NHANES is not in operation for about two weeks at New Years and for about two weeks in the summer.

A second dietary recall (DR) interview by telephone will be scheduled 3-10 days after the sample person's MEC exam for examinees who had the first DR. A set of measuring guides (including a USDA food model booklet, a ruler, a set of household spoons, and a set of measuring cups and measuring spoons), an appointment reminder card with the date and time of the scheduled interview, and a phone contact number will be given to the participants at the end of their MEC dietary interview. The second DR (Attachment 3h) will be conducted using the USDA's automated DR system, which is also used in the MEC. After successful completion of the second dietary recall on the phone the participant will be remunerated as detailed in Section A.9.

Sample Design

Non-Hispanic Blacks, Non-Hispanic non-black Asians, Hispanics, and low income non-Hispanic non-black non-Asian white/other persons will continue to be oversampled. Because NHANES exam sessions are designed to be no more than 4 hours long only about 5000 examinations can be conducted per year.

As with previous NHANES surveys, the design for NHANES 2019-20 is a stratified, multistage area probability sample of the civilian non-institutionalized population of the United States. The stages of the sample selection are first: selection of Primary Sampling Units (PSUs) (a county or a group of contiguous counties); second: segments within PSUs (a block or group of blocks containing a cluster of dwelling units); third: dwelling units within segments; and fourth: participants within occupied dwelling units.

NHANES will have two examination teams that operate continuously and travel from one PSU to another approximately every 6 weeks in a given year. Because of the time required for setting up, dismantling, relocating, and calibrating equipment, it has been determined, from previous NHANES that the MECs must be at each location for at least 4 weeks to be operationally feasible and cost effective. An upper bound of 8 weeks at each location was established to have an adequate number of PSUs for producing acceptable between-PSU sampling variances. The operational and statistical constraints result in an expected sample of 5,000 examined persons and 15 PSUs per year for NHANES.

Selection of Primary Sampling Units (PSUs)

To determine a probability of selection for each PSU, a measure of size (MOS) based on the most recently available projection from Census data is established for each PSU. The MOS reflects the distribution of the population in the PSU across the race and Hispanic origin-income categories of interest. For the 2019-2020 sample, these are Hispanics, non-Hispanic blacks,

non-Hispanic non-black Asians, non-Hispanic, non-black, non-Asian, low income whites and others and non-Hispanic non-black non-Asian non-low income whites and others.

Selection of Sample Persons within Households

The sample of persons is obtained by interviewers going to the occupied dwelling unit and screening household members, based on their demographics. Participants are then selected based on the demographic selection probabilities.

The subdomains are identified in Table 1 of attachment 14a. Each race and Hispanic origin, gender, and age-specific row is a subdomain of interest for NHANES. To achieve desired minimum sample sizes for each domain, sampling rates have been calculated based upon optimum allocation for the subdomain in each race and Hispanic origin group that requires the highest sampling rate to achieve the desired sample size. All screened persons in the subdomain used for optimum allocation are retained in the sample. The screened persons in other subdomains are subsampled to bring the samples down to the desired levels. Subsampling is needed to achieve the required sample sizes by age, gender, and race and Hispanic origin. Experience with NHANES and the Hispanic Health and Nutrition Examination Survey (HHANES) has indicated that response rates are improved when larger sample sizes within households are used. Therefore, the method of subsampling developed will increase the number of sample persons per household. A computer program loaded into the tablet computer carried by the interviewers doing the household screening indicates to the interviewer which persons are sampled.

Estimation

To produce unbiased cross-sectional estimates for the civilian, noninstitutionalized population of the United States, the sample data will be inflated to the level of the population from which the sample is drawn. As in previous NHANES, the sampling weight for each sample person will be the product of three factors: the reciprocal of the probabilities of selection (PSU, segment, household, person); an adjustment for nonresponse; and a poststratification adjustment factor to make the resulting survey estimates in each age, sex, race, and Hispanic origin category approximately equal to independent control totals from the American Community Survey (ACS) conducted by the U.S. Bureau of the Census.

Variances for NHANES can be estimated using a number of procedures and software programs. To allow for the computation of variance estimates, sample design variables are included on the public use data files. These variables are analogous to the typical stratum and PSU variables that were used in NHANES III, but the current design variables have been "masked" to limit the possibility of geographic disclosure. Masked design variables have been used by NHANES since the 1999-2000 data release. Examples of widely available software programs capable of producing variance estimates from complex surveys include: SUDAAN (Research Triangle Institute), WesVar (Westat), SAS Survey Procedures (SAS Institute), STATA (StataCorp) and R Survey Package (Lumley).

Analytic guidelines are provided on the NHANES website at http://www.cdc.gov/nchs/data/series/sr_02/sr02_161.pdf and http://www.cdc.gov/nchs/data/nhanes/analytic_guidelines_11_12.pdf to provide a broad overview of the statistical and methodological issues the user needs to be aware of when analyzing data from a complex, continuous survey like NHANES. These are updated and expanded periodically.

Quality Control

Two primary sources of error enter into a survey such as NHANES: sampling error and non-sampling error. Both types of errors can affect the estimates produced from the survey and may lead to a substantial loss in precision in statistical tests. Therefore, an extensive quality control system is a critical element in the operation of NHANES. The objective of the NHANES quality control program is to minimize measurement errors, to control them, or to measure these errors.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Interviewers have access to a variety of materials to assist them in sample person induction and nonresponse conversion. There is a follow-up letter that is, when possible, customized to fit the circumstance of each individual sample person who refuses the interview, examination or both. Attachment 8a contains the generic version of this letter. In addition to the follow-up letter that is sent to every potential sample person who refuses (see Attachment 8a), interviewers have additional tools such as: "NHANES at a Glance" and "Obtaining Respondent Cooperation." "NHANES at a Glance" contains articles from newspapers, journals, and letters of endorsements to show the sample person. "Obtaining Respondent Cooperation" contains general interviewing approaches and techniques for especially challenging conversions.

Other methods to maximize response include:

- Arrange for free transportation to MEC for sample persons or for incentives to help cover out of pocket expenses
- Allow a companion (parent, caregiver, etc.) to accompany participant through the exam
- Provide a report of examination of findings
- Bilingual staff (Spanish)
- Interpreters for languages other than Spanish
- Advance publicity and contact with/endorsements from community leaders and groups
- Sampling multiple individuals in a household
- Flexible examination schedule including evenings and weekends
- Telephone reminders before scheduled appointments
- Customized follow-up efforts
- Recorded clips for TV stations
- General and population specific brochures about the survey (See Attachments 17a and 17b for an example of each.)
- Multimedia presentation on interviewers' tablet computers
- Evaluative studies of response where appropriate
- A website page dedicated specifically for survey participants
- Development of the "Make a Plan" tracker tool which serves as a reminder for participants to complete each stage of the survey (see Attachments 18a and 18b)

If sample persons are apprehensive or reluctant to participate in the examination, there are a number of techniques that can be employed by the interviewer once a reason for non-cooperation has been determined. Some techniques are the same as those used to convince sample persons to participate in the household interview while others are unique to the examination component.

During the interviewing process there are multiple contact attempts made by the interviewer to

conduct the screener interview or household person interview

For sample persons who have scheduled an examination appointment, a reminder is sent in advance. Additionally, within forty-eight hours of their examination appointment, all sample persons receive a reminder telephone call. For sample persons who do not have phones, whose phones are not working, or who have not been contacted by phone for some other reason, a home visit is made. If the contact attempts are unsuccessful, an appointment slip is left at the household for each sample person. If a sample person cancels an examination appointment, recontact is made immediately.

We are continuing the following steps to improve response rates:

- Since May of 2016, the contractor and staff from NCHS have held bi-monthly meetings to stimulate fresh strategies to address declining response rates.
- Increased efforts (e.g., new advertising and outreach sources, etc.) to recruit and train more qualified/experienced full time and backup household interviewers. For example, we continue to work with the Asian Pacific Islander American Health Forum in developing advertisements to recruit Asian staff to the NHANES field operations.
- Enhancement of the “obtaining cooperation” portion of the initial interviewer training and Interviewer Manual to include more “real life” practice modules.
- In 2010 we began a concentrated effort to increase our focus on refusal conversion trainings. At the mid-year 2010 training we added a session on cultural sensitivity and best approaches to use when working with the Asian population. This training was repeated at the 2011 annual retraining to include all field staff. Later in 2011 we enhanced the training to include a broader focus on all our oversampled populations (Asians, African-Americans, and Hispanics). In 2012, we continued our efforts to increase response rates by focusing on the issues related to soliciting participation from the 60 and older population group. And currently in 2018, we are retraining field interviewers to sharpen their door step presentation skills and arming them with talking points to combat real-day concerns about participation.
- Supervisory field staff are encouraged to provide more one-on-one interviewer training at the field offices on refusal conversion strategies.
- The Listers, staff who visit PSUs at least four months prior to the opening of stands, are asked to provide more information about every segment they visit so that we can address potential problems as early as possible, especially locked buildings, gated communities, and college campuses.
- The Advance Team addresses community support beginning with their earliest contacts with community leaders.
- NCHS works with the contractor in an effort to obtain more media coverage at every sampled PSU.
- The contractor provides NCHS with additional names of prominent people and

organizations which could assist with endorsements.

- The contractor obtains more local endorsements for every stand beginning as early as four months prior to the start of a stand.
- The NHANES operations branch works more closely with contractor to assist in obtaining community and national endorsements in support of the survey.

Should the above efforts lead to changes in outreach\background\administrative materials etc. or to the development of new materials for use in NHANES, then the program would submit a non-substantive.

4. Tests of Procedures or Methods to be Undertaken

The current continuous operation of NHANES presents unique challenges in testing new components. As protocols and systems are designed and developed, they are fielded. Each examination component is operationalized and evaluated for feasibility of exam room arrangement and procedures, performance of equipment, efficiency, completion times and interaction with the system. Procedures are conducted with trained examiners and actual subjects of the required ages to ensure accurate testing of the components and systems. Standard operating procedures are evaluated for efficiency and coordination of subject flow through the MEC, completion of required exam components, subject cooperation and refusal conversion, staff productivity, and adequacy of facility and supplies. NCHS staff, the contractor's development staff and consultants participate in the evaluation effort.

In certain cases, additional testing using non-NHANES respondents may be necessary. This could occur, for example, when the NHANES is developing a method to be used in the survey that can be tested or calibrated outside the NHANES survey setting. For example prior to pilot testing a NHANES 24 hour urine collection within the survey, a calibration study was done with volunteers who received an incentive.

There may also be a need to conduct testing within NHANES for projects that may supplement/compliment NHANES or that may be implemented in alternative settings such as within other health studies, in home environments or in non-NHANES subgroups. For example in 2012, NHANES conducted a Health Measures at Home Methodology Study (HMHS) among a small subset of NHANES participants. This involved collecting height, weight, blood pressure and dried blood spots both in NHANES participants' homes and in the NHANES MEC. This project was conducted because NCHS sought to investigate the feasibility of incorporating physical measures and biologic specimen collection into the National Health Interview Survey (NHIS) (OMB No. 0920-0214, Exp. Date 12/31/2020) by implementing the HMHS within NHANES.

Summary of 2017-18 NHANES Developmental Projects

The following developmental projects were approved to be conducted during NHANES 2017-18 in advance of potential inclusion to the content of or procedures for the 2019-20 NHANES or beyond.

- Words-In-Noise (WIN) (Attachment 4)
- Balance/ vestibular/visual function (Attachment 4)
- Blood Collection – Infants < 1 year old

The WIN and Balance/vestibular/visual function pilots have been completed. Please see Attachment 4 for the reports on the results of these projects. The pilot of blood collection in infants less than 1 year old will begin later in 2018. In order to have a large enough sample, this project will continue into 2019. A report on this project will be provided, after data collection is complete.

Future Developmental Projects to be conducted during NHANES 2019-20

NHANES expects to plan future developmental projects for testing or implementation within the NHANES 2019-20 environment. The projects include non-response related initiatives such as:

- Develop media/social media products such as respondent participation videos including a Video MEC Tour narrated by the NHANES Medical Officer and a Participant Testimonial Video (the plan is to use non-SP Dry Run participants); Facebook and Instagram pilot projects; and radio advertisements
- Create a more simplified/user friendly Website Participant Page
- Develop a new advance material mailing protocol with updated materials and an optimized incentive structure
- In conjunction with the update to the advance protocol, test and implement (if successful) a new incentive structure that includes staggering incentives across participation levels
- Develop new letters, postcards and other materials for refusal conversion after results of focus group testing (which began in April 2018 under OMB Control No. 0920-0222, Exp. 07/31/2018)
- Conduct crossover or bridge studies, as needed, when equipment needs replacing in the MECs (due to aging technology, improved methods or advancements in technologic capabilities of newer equipment etc.)

For these projects and any currently unforeseen developmental projects related to future NHANES content, a non-substantive change package or GenIC request (under the approved package OMB Control No. 0920-1208, Exp. 12/31/2020) would be submitted to OMB before undertaking the project.

For these projects and any currently unforeseen developmental projects **not** related to future NHANES content (e.g., a project done for a different survey, such as a community HANES), a non-substantive change package, GenIC, (under the approved package OMB Control No. 0920-1208, Exp. 12/31/2020) or a full revision, as appropriate, would be submitted to OMB before undertaking the study.

Special Studies and Additional Health and Nutrition Studies

This request also seeks permission for the Division of Health and Nutrition Examination Surveys (DHANES) to plan, or test components for special studies or additional components outside the current NHANES sample. Such projects could directly relate to the future or current content of NHANES. An example might be testing wearable devices among volunteers first, to assess the potential of using such devices in NHANES. Or such projects could relate to studies complimentary to NHANES. An example might be a follow-up of past NHANES participants or studies like the 2012 NHANES National Youth Fitness Survey (NNYFS). Or such projects could

relate to the content of other health and nutrition studies, such as a community HANES for example. A future example might be testing new dual-energy x-ray absorptiometry (DXA) equipment among volunteers in preparation for replacing aging equipment in the field.

NHANES is including burden hours to accommodate developmental projects and special studies (Attachment 12) involving up to 3,500 persons (Section A12, Table 1, line 5). NHANES understands that submitting a nonsubstantive request to OMB for clearance would be required before starting such projects.

NHANES is including burden hours to accommodate a 24-hour blood pressure pilot (Attachment 13). This project may involve up to 1,000 additional persons (Section A12, Table 1, line 6). NHANES understands that submitting a nonsubstantive request to OMB for clearance would be required before starting such projects.

Nonresponse Investigation

Nonresponse investigations under DHHS task order contracts or other contract mechanisms may be necessary should nonresponse rates make that advisable. Details of any such investigations that involve public participation will be described under a non-substantive change package using burden from developmental projects.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

1) The following persons were consulted in the statistical aspects of the design of the NHANES:

Jennifer D. Parker, Ph.D.
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Centers for Disease Control and Prevention
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2) The following person is responsible data collection activities:

Kathryn S. Porter, MD, MS, FACPM
Captain, U.S. Public Health Service
Director, Division of Health and Nutrition Examination Surveys
National Center for Health Statistics
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Phone: 301-458-4441

3) The following person is responsible for analysis of the NHANES data:

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