

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..... 2
 - 1. Respondent Universe and Sampling Methods..... 2
 - 2. Procedures for the Collection of Information..... 5
 - 3. Methods to Maximize Response Rates and Deal with Nonresponse 11
 - 4. Tests of Procedures or Methods to be Undertaken..... 13
 - 5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data..... 14

NHANES – Supporting Statement – Section B.

B. Collection of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

The sample design of the National Health and Nutrition Examination Survey (NHANES) is based on a continuous on-going annual survey of the non-institutionalized, civilian population of the U.S. Each single year and any combination of consecutive years comprise a nationally representative sample of the U.S. population. This design will allow limited national estimates from NHANES every two years.

Table 1 shows the sampling domains for NHANES. These domains represent the sampling subpopulations of interest. For NHANES 2015-2018, there are 87 sampling domains defined by race and Hispanic origin, gender, age, and by low income status (i.e., households in which the household income is below 130% of the poverty level) for the non-Hispanic white/other domains.

Table 1 shows the annual and cumulative estimates of the target sample sizes by sampling subdomain, based on the assumption that two Mobile Examination Center (MEC) teams will be in operation and approximately 5,000 persons will be examined in 15 primary sampling units (PSUs) per year. The expected sample size is based on past NHANES experience with response rates for each subdomain of interest. The goal for the overall examination response rate for NHANES 2015-2018 is 70 percent, which is slightly lower than past years. In NHANES 2011, 2012 and 2013, the examination response rates were 71, 66 and 70 percent, respectively.

Table 1: Projected population size, number of sampled persons, and projected response rates for NHANES 2015-2018 in 60 PSUs by age, race and Hispanic origin, income, and gender

			Projected population average over years 2015-2018 ¹	Total sample	Estimated exam response rate ²	Target number of exams for 2015-2018
Black, non-Hispanic	M&F	< 1 year	726,585	216	85%	184
		1-2 yrs.	1,439,050	370	83%	308
		3-5 yrs.	2,092,808	387	80%	308
	M	6-11 yrs.	2,010,582	383	80%	308
		12-19 yrs.	2,557,093	390	79%	308
		20-39 yrs.	5,531,423	665	74%	492
		40-49 yrs.	2,247,656	343	71%	244
		50-59 yrs.	2,379,097	351	69%	244
		60+ yrs.	2,758,652	804	63%	504
	F	6-11 yrs.	1,953,238	384	80%	308
		12-19 yrs.	2,544,785	401	77%	308
		20-39 yrs.	6,421,630	656	75%	492
		40-49 yrs.	2,752,614	339	72%	244
		50-59 yrs.	2,848,545	327	75%	244

NHANES – Supporting Statement – Section B.

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		60+ yrs.	3,836,365	788	64%	504
Total Black, non-Hispanic			42,100,123	6,806	73%	5,000
Hispanic	M&F	<1 year	1,171,535	334	86%	288
		1-2 yrs.	2,316,621	333	87%	288
		3-5 yrs.	3,362,637	353	82%	288
	M	6-11 yrs.	3,225,375	338	86%	292
		12-19 yrs.	3,943,976	356	82%	292
		20-39 yrs.	9,528,110	720	68%	492
		40-49 yrs.	3,804,496	330	75%	248
		50-59 yrs.	2,827,360	364	68%	248
		60+ yrs.	2,659,160	814	61%	496
	F	6-11 yrs.	3,086,758	357	82%	292
		12-19 yrs.	3,783,981	371	79%	292
		20-39 yrs.	8,777,249	613	80%	492
		40-49 yrs.	3,721,308	324	76%	248
		50-59 yrs.	2,865,586	339	73%	248
		60+ yrs.	3,259,775	881	56%	496
Total Hispanic			58,333,927	6,828	73%	5,000
Non-Hispanic, non-Black Asian	M&F	< 1 year	273,292	79	66%	52
		1-2 yrs.	546,059	162	62%	100
		3-5 yrs.	804,702	241	66%	160
	M	6-11 yrs.	784,302	237	61%	144
		12-19 yrs.	978,909	292	64%	188
		20-39 yrs.	2,868,204	554	58%	324
		40-49 yrs.	1,325,307	326	50%	164
		50-59 yrs.	1,060,302	319	50%	160
		60+ yrs.	1,318,080	397	46%	184
	F	6-11 yrs.	758,637	223	50%	112
		12-19 yrs.	960,905	288	61%	176
		20-39 yrs.	3,087,674	571	55%	316
		40-49 yrs.	1,519,346	314	51%	160
		50-59 yrs.	1,226,492	287	56%	160
		60+ yrs.	1,707,959	508	39%	200
Total non-Hispanic, non-Black Asian			19,220,170	4,800	54%	2,600
Non-Hispanic White/Other	M&F	< 1 year	475,509	140	97%	136
Low Income		1-2 yrs.	922,061	169	81%	136
		3-5 yrs.	1,346,124	154	91%	140
	M	6-11 yrs.	1,216,699	150	93%	140
		12-19 yrs.	1,469,297	151	93%	140
		20-29 yrs.	2,120,036	141	76%	108
		30-39 yrs.	1,384,933	127	85%	108
		40-49 yrs.	1,253,827	128	84%	108

NHANES – Supporting Statement – Section B.

Table 1: Projected population size, number of sampled persons, and projected response rates for NHANES 2015-2018 in 60 PSUs by age, race and Hispanic origin, income, and gender						
		50-59 yrs.	1,492,999	149	70%	104
		60-69 yrs.	1,257,791	146	71%	104
		70-79 yrs.	628,636	162	64%	104
		80+ yrs.	401,776	122	52%	64
	F	6-11 yrs.	1,144,717	158	89%	140
		12-19 yrs.	1,467,306	171	82%	140
		20-29 yrs.	3,015,976	123	84%	104
		30-39 yrs.	1,956,563	117	89%	104
		40-49 yrs.	1,457,591	115	90%	104
		50-59 yrs.	1,841,567	124	84%	104
		60-69 yrs.	1,690,869	145	72%	104
		70-79 yrs.	1,354,362	130	80%	104
		80+ yrs.	1,273,741	203	51%	104
Total non-Hispanic White/Other Low Income			29,172,380	3,028	79%	2,400
Non-Hispanic White/Other	M&F	< 1 year	1,657,990	395	73%	288
Not Low Income		1-2 yrs.	3,358,271	519	56%	288
		3-5 yrs.	5,020,468	449	64%	288
	M	6-11 yrs.	5,336,202	423	69%	292
		12-19 yrs.	7,829,377	413	71%	292
		20-29 yrs.	10,253,435	351	60%	212
		30-39 yrs.	10,708,541	361	59%	212
		40-49 yrs.	10,911,032	346	61%	212
		50-59 yrs.	13,237,738	364	58%	212
		60-69 yrs.	11,863,100	357	59%	212
		70-79 yrs.	6,916,646	399	53%	212
		80+ yrs.	3,292,269	450	47%	212
	F	6-11 yrs.	5,089,881	401	73%	292
		12-19 yrs.	7,429,312	434	67%	292
		20-29 yrs.	9,355,737	388	55%	212
		30-39 yrs.	10,317,801	336	63%	212
		40-49 yrs.	10,882,958	307	69%	212
		50-59 yrs.	13,380,811	348	61%	212
		60-69 yrs.	12,395,307	351	60%	212
		70-79 yrs.	7,350,344	408	52%	212
		80+ yrs.	4,297,525	513	41%	212
Total non-Hispanic White/Other Not Low Income			170,884,743	8,312	60%	5,000
Total non-Hispanic White/Other			200,057,123	11,339	65%	7,400
TOTAL			319,711,342	29,773	67%	20,000

Table 1: Projected population size, number of sampled persons, and projected response rates for NHANES 2015-2018 in 60 PSUs by age, race and Hispanic origin, income, and gender

¹ Population of interest is the civilian noninstitutionalized population in the 50 United States and the District of Columbia.

² Response rates are the domain-level response rates (number of examined persons divided by the number of identified sampled persons) from the 2011-2012 experience, each adjusted downward by the overall screener response rate experienced in those years to result in conservative estimates.

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 and other units of the sample design
- list the segments selected
- make advance arrangements for each location
- provide input on NCHS's publicity/outreach methods and materials
- set up and maintain field offices
- set up and maintain the MECs
- translate all questionnaires into Spanish, Chinese, Korean and Vietnamese
- hire the field staff
- create manuals and training programs for all field procedures (including training in NCHS confidentiality guidelines and regulations)
- train the field staff members
- list the households to be sampled
- select the sample
- 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 interview and examination data to NCHS.

A complete blood count (CBC) and pregnancy test will be conducted in the MEC laboratory and biological specimens will be shipped to several laboratories in the United States for analysis.

After the listing procedure (driving each block in the sample to list all buildings), which identifies households to be potentially included in NHANES, a pre-Advance Letter postcard and an Advance Letter 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 1, solely to determine eligibility (Screening is described in more detail in B.2. Selection of Sample Persons within Households). The interviewer next explains the household questionnaires to all eligible 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

NHANES – Supporting Statement – Section B.

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 (Attachment 5), 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.

(Note regarding informed consent for those unable to read the consent form. If the interviewer discovers the participant to be illiterate or visually impaired, the interviewer reads the entire document to the person in front of a witness. Any questions are answered 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 household screener and interview questions appear in Attachment 8. The Family Relationship Questionnaire is administered first, followed by the Sample Participant (SP) and Family questionnaires. The Sample Participant and Family Questionnaires are recorded for quality control purposes. Verbal consent is obtained/recorded at the beginning of the recording.

When the interview is completed, the interviewer reviews with the participant the examination informed consent brochure (Attachment 5), which contains detailed information about the examination. 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 office to make the examination appointments. The interviewer informs the participants that they will receive remuneration for participating in the examination, as well as reimbursement for transportation expenses and childcare, if necessary. A suggested introduction to remuneration is in Attachment 4. If the participant has questions or can't come at the randomly assigned time the interviewer will provide additional information. As part of explaining the remuneration the interviewer will inform the participant that they will receive a larger remuneration if they come to the examination center at the time of day that they are randomly assigned to attend. Additionally, the interviewer may mention that participation in components occurring after the examination (2nd dietary recall by phone) will also result in remuneration.

When participants arrive at the MEC, the Coordinator (receptionist) greets them and verifies identifying information. Next, the participant is given a pair of disposable pajamas, slippers, and a urine cup before starting their examination. In addition to the Coordinator, the survey team at each center consists of a physician, two dietary interviewers, three certified medical technologists, four health technicians (at least two of whom are radiological technicians), one certified phlebotomist, two interviewers, a dentist and a facility equipment specialist.

The examination data collection forms are in Attachment 8. Upon completion of the examination, each examinee is remunerated, as detailed in Section A.9. Some of the medical findings of the examination are given to the examinees before they leave the MEC. Other results are mailed to them later, as results are made available from the laboratories or data graders. The sexually transmitted disease (STD) laboratory test results are reported to participants by telephone when they call NCHS for the results and provide the personalized

NHANES – Supporting Statement – Section B.

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 9.

The examination centers will be open five days each week, with closed days changing on a rotating basis so that appointments will be available on any day of the week. This rotating schedule will also allow collection of dietary recall data across all days of the week, since eating patterns are known to vary for workdays, school days, holidays and weekends.

There will be two examination sessions at the MEC each day, held morning, afternoon, or evening, for the convenience of participants. At any given time during the survey, examinations will be conducted at two survey locations simultaneously, for eleven months of the year, with breaks of about two weeks at New Years and about two weeks in the summer. This will require field office and household interviewing staff to support two complete examination teams throughout NHANES.

A second dietary recall (DR) interview by telephone will be scheduled 3-10 days after their 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 will be conducted using the USDA's Automated Multiple Pass Method DR system that 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, Asians, Hispanics, and low income non-Hispanic white/other persons will continue to be oversampled. The restrictions imposed by the NHANES examination permit only about 5000 examinations per year.

As with previous NHANES surveys, the design for NHANES 2015-2018 is a stratified, multistage 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 over each year of data collection and travel from one PSU to another approximately every 6 weeks. 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 (20,000 persons and 60 PSUs for the years 2015-2018).

Selection of Primary Sampling Units (PSUs)

PSUs for NHANES 2015-2018 have been selected as described below. 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 2015-2018 sample, these are Hispanics, non-Hispanic blacks, Asians, and low-income whites and others.

After assignment of the PSU MOS, the counties with the largest MOS are included in the sample with certainty. For 2015-2018, there are two certainty PSUs, one of which comprises three of the 60 study locations. The remaining non-certainty PSUs are grouped into 14 major strata. The major strata are based on state groupings defined by their health-related measures, and then formed by the geographical and urban-rural characteristics of the PSUs within each state group. Four PSUs are selected from each major stratum yielding 56 noncertainty PSUs for a four-year period and a total of 60 study locations for a four-year sample.

To calculate national estimates for both single and multi-year time periods, the four PSUs within each major stratum are assigned to study years. The four ordered PSUs within a major stratum are labeled as A, B, C, and D. A and B, and C and D are paired. One PSU of each pair is randomly selected and randomly allocated to 2015-2016 or 2017-2018. The other PSU of the pair is assigned to the other two year period. For each of the 14 major strata, once the two PSUs of the stratum for 2015-2016 are allocated, a PSU is randomly selected for 2015 or 2016. The two remaining PSUs in each major stratum are assigned to the comparable year in 2017-2018. For example, if B is assigned to 2015, then A is assigned to 2017. If C is assigned to 2016 then D is assigned to 2018. The randomness of both pair-wise selection and annual assignment yields a stratified national sample for the four-year period 2015-2018; national samples for 2015-2016 and 2017-2018 that are balanced with respect to the stratification variables; and annual samples that are nationally representative and balanced with respect to the stratification variables (but subject to larger sampling errors).

Selection of Segments and Households within PSUs

The MOS of a segment is calculated in a similar manner as for PSUs. However, the income level within a segment is excluded from the segment MOS since these data are not available at the sub-PSU level. The actual probability of selection of a segment depends on the MOS of the segment, the MOS of the PSU, and the total MOS of the stratum from which the PSU is selected. The segments are selected with probability proportionate to size, with the MOS for 2015 and 2016 as well as for 2017 and 2018 based on Census 2010 population data.

Research on intraclass correlations and unit costs has indicated that an average of 14 examinees per segment is close to optimum for most statistics in NHANES. Operational constraints require approximately equal number of examined SPs per study location -- about 340 in most locations. The total number of sample segments within the PSUs is expected to be 1,440, an average of 24 per study location

After listing all dwelling units within the sampled segments, a sample of dwelling units is selected that is 80% larger than what is expected to yield desired number of participants. This sample is then divided into release groups. Each group is a systematic subsample of the full dwelling unit sample, with the dwelling unit sample sequenced by segment number and a temporary, geographically based sequence number prior to subsampling. Thus, each release group contains cases from all segments, except as limited by release group and segment size.

In most PSUs the first, and largest, release group is released to the interviewers initially. The

NHANES – Supporting Statement – Section B.

yield from this group is monitored and used to project estimates of the total yield of sampled participants expected from this group. Based on these figures, additional groups (or portions of groups) are released as needed. The sample is monitored on a daily basis to determine whether additional release groups are required.

Selection of Sample Persons within Households

The sample of persons is selected by subsampling persons within occupied dwelling units to obtain the desired sample sizes.

The subdomains are identified in Table 1. 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 entire 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 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), and STATA (StataCorp).

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.

Additionally, NCHS has web-based tutorials (<http://www.cdc.gov/nchs/tutorials>) designed to meet growing demands of NHANES data users and promote broader and more proficient use of NHANES data. This self-learning tool, initially developed in conjunction with the National Cancer Institute (NCI), covers the whole process of analyzing continuous and historic NHANES data, by combining step-by-step instructions with actual examples of statistical programs and outputs, complemented with a quiz and exercises. Main topics include how to prepare analytical data files such as locating variables of interest, merging data files, using appropriate sample weights, as well as how to generate statistical estimates with SAS, SUDAAN, and STATA software. It is designed to benefit individuals new to using NHANES data as well as experienced NHANES data users.

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 eliminate measurement errors, to control them, or to measure these errors.

Sampling errors occur when data are collected from a sample of the population rather than a complete census. The errors arise at all stages of sampling from selection of PSUs to identification of individual sample persons. Errors in the sampling process may result in non-coverage or incorrect coverage of persons or places. Careful planning and execution of the sampling design at each stage will reduce the sampling error. In surveys like NHANES, selection of PSUs, dwelling units and sample participants are done prior to the survey to eliminate bias in the selection process. Extensive quality control procedures are carried out during the sampling process.

Non-sampling errors arise during data collection from sources such as measurement and recording errors in examination, coding of the results, interviewers' mistakes during interviews, recall problems, poor questionnaire design or problems with translations. Since the National Health Examination Surveys (NHES) surveys were conducted in the 1960s, basic quality control procedures have evolved through NHANES I, NHANES II, HHANES, and NHANES III, depending on the content of the examination and technology available. NHANES continues to build on these past experiences. In addition to the procedures used in these previous surveys, NHANES uses an automated sample selection program during the screening phase of the household contact, an automated household interview and an automated data collection system for data entry in the examination phase of the survey with built-in quality control checks and edits. To reduce non-sampling error, NCHS staff are employing the following strategies: field editing, rigorous staff training and periodic retraining with feedback mechanisms, certification of examiners, standard environment, calibration of equipment on regular basis, multiple readings if possible, monitoring of field procedures by headquarters staff, comparison of findings by technicians over time. All laboratory samples are analyzed by certified contract laboratories and standard quality control procedures are used such as blinded split samples and random repeat testing. Data from household questionnaires are carefully entered, verified, validated and edited by experienced field staff and programmers. The household questionnaire validation forms and procedures are included in the Attachment 8.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Interviewers have access to a variety of materials they use to assist them in sample person 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 4 contains the generic version of this letter. Some examples of situations where this letter may be customized to address an individual are, a mother with childcare needs, a person who refuses due to scheduling issues or time constraints, a person who doesn't trust the government, etc. In addition to the follow-up letter that is sent to every potential sample person who refuses the interview, examination or both (see Attachment 4), interviewers also have two manuals that serve as a reinforcement to the process: "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 hard-core conversions.

Other methods to maximize response include:

- Remuneration of sample persons
- Reimbursement for transportation costs or free transportation to MEC
- Allow a companion (parent, caregiver, etc.) to accompany participant through the exam
- Provide a report of examination findings
- Bilingual staff (Spanish)
- Interpreters for languages other than Spanish
- Advance publicity and contact with/endorsements from community leaders and groups
- Post cards prior to advance letter
- Sampling multiple individuals in a household
- Flexible examination schedule including evenings and weekends
- Telephone reminders before scheduled appointments
- Intensive follow-up efforts
- Recorded clips for TV stations
- Population specific brochures about the survey
- Multimedia presentation on interviewers' tablet computers
- Evaluative studies of response where appropriate
- A website page dedicated specifically for survey participants

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. Generally, after two unsuccessful attempts, the interviewer places a call-back card at the doorstep of the potential sample person's home.

For sample persons who have scheduled an examination appointment, a reminder notice is mailed one week in advance. Additionally, within forty-eight hours of their examination appointment, all sample persons receive a reminder telephone call. For sample persons who

NHANES – Supporting Statement – Section B.

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.

A follow-up letter is sent to sample persons who refuse the household interviews or MEC examinations and to sample persons who have been difficult to contact. The letters are tailored to fit each sample person's particular circumstance. Examples of letters are included in Attachment 4.

We are continuing the following steps to improve response rates:

- Increased efforts (e.g., new advertising/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 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.
- Supervisory field staff are encouraged to provide more one-on-one interviewer training at the field offices on refusal aversion/conversion.
- Listers, 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.
- Advance Team addresses community support beginning with their earliest contacts with community leaders.
- NCHS works with the data collection Contractor in an effort to obtain more media coverage at every sampled PSU.
- Contractor provides NCHS with additional names of prominent people and organizations which could assist with endorsements.
- Assigned Contractor project person obtains more local endorsements for every stand beginning as early as two months prior to the start of a stand.
- NCHS operations branch works more closely with Contractor to assist in obtaining community and national endorsement and support for the survey

4. Tests of Procedures or Methods to be Undertaken

Much of the content of the proposed NHANES field operations were part of previous NHANES. This includes operational features such as listing and screening, sections of the questionnaires and components of the examination.

The questionnaire items in NHANES came from many sources that ensured adequate testing of the wording of the questions and selection of appropriate response categories. Many questions were taken from the National Health Interview Survey (NHIS) core questionnaires (OMB No. 0920-0214). These questions have been tested in the NCHS Questionnaire Design Research Laboratory (QDRL) (OMB No. 0920-0222) and then used in the field with thousands of respondents. Additional NHANES questions were derived from standard instruments and tests as well as surveys done by other agencies and organizations. Examples of these are the dietary questions and the mental health module. Still other NHANES questions were taken from previous NHANES surveys.

Examination components have been included in previous NHANES and/or other population based studies. A criterion for inclusion of examination content for the early years of NHANES was the existence of a standardized procedure for use on NHANES. To incorporate new content in future years of the continuous NHANES, evaluation of objective data collection procedures used in other studies and testing of new procedures concurrent to NHANES data collection will be required. This testing may be done within the NHANES field operations or as a standalone study not using NHANES participants. All laboratory methods used in NHANES have been tested and deemed reliable and valid prior to their inclusion in NHANES.

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 remunerated volunteers.

Pilot Tests for the 2015-16 NHANES

Only one pilot test was conducted for potential inclusion in the 2015-16 NHANES. That was a pilot test on collecting a urine specimen during the MEC examination on children ages 3-5.

The pilot was successful. Ninety-eight percent of the 3-5 year olds provided a urine sample and 81% were able to provide our target of 60 ml or more of specimen. One-hundred and twenty-one children had some urine for testing. Their results were reviewed to determine if their results were above the level of detection and similar to 6-8 year olds results from the 2011-12 NHANES. The comparison was not statistical but qualitative. Results were from these classes of chemicals: heavy metals and iodine; phenols and phthalate metabolites; phytoestrogens; polycyclic aromatic hydrocarbon metabolites; tobacco biomarkers (including NNAL and volatile nitrosamines); and volatile organic compounds. In 2015-16 we plan to include urine specimens for children ages 3-5 in the protocol. In contrast to ages 6 and older where only a 1/3 sample are tested for the environmental chemicals all children 3-5 will be sampled because of the small size of this age domain.

Methodological Studies to be conducted during NHANES 2015-16

NHANES expects to conduct several methodological studies during 2015-16. Possibilities include tests such as:

- Ankle Brachial Pressure Index
- Peripheral neuropathy
- Fundus photography
- Digital photographs of dietary supplement and/or prescription medication container labels
- Collection of an unsmoked cigarette from smokers for laboratory analysis.
- Ambulatory blood pressure monitoring
- Waist circumference using multiple methods
- Pilot test the procedures to be used to recontact participants at 6, 12, 18 and 24 months to assess persistence, disappearance and acquisition of oral HPV infection. The testing would be of the mailing and recontact procedures.

For these projects and any currently unforeseen methodological studies, a non-substantive change package would be submitted to OMB before undertaking the study.

Pilot Tests to be conducted in 2015-16 for the 2017-18 NHANES

The survey expects to continue conducting pilot studies for future cycles of continuous NHANES. During 2015-2016, pilot studies will be conducted to prepare for implementation during NHANES 2017-2018. A non-substantive change package would be submitted to OMB before undertaking any pilot study.

Special Studies and Additional Health and Nutrition Examination Studies

This request also seeks permission for NCHS to plan and test additional Health and Nutrition Examination components outside the current sample. Such a project would directly relate to the future or current content of the NHANES.

NCHS is including burden hours to accommodate such special studies (Attachment 10) involving up to 2,500 participants (Section A12, Table 1, line 2), however, NCHS understands that such special studies would require submission of a full revision to OMB for clearance.

Nonresponse Investigation

NHANES – Supporting Statement – Section B.

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 pilot or methodological studies.

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

1) The following person was consulted in the statistical aspects of the design of the NHANES:

Clifford L. Johnson
Mathematical Statistician
Division of Health and Nutrition Examination Surveys
National Center for Health Statistics
Centers for Disease Control and Prevention
Phone: 301-458-4292

2) The following person is responsible data collection activities:

Vicki L. Burt
Chief, Planning Branch
National Center for Health Statistics
Centers for Disease Control and Prevention
Phone: 301-458-4127

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

Vicki L. Burt
Chief, Planning Branch
National Center for Health Statistics
Centers for Disease Control and Prevention
Phone: 301-458-4127

NHANES – Supporting Statement – Section B.

- Attachment 1 – Applicable Laws or Regulations (Excerpts)
- Attachment 2a – Federal Register Notice
- Attachment 2b- Responses to Federal Register Notice
- Attachment 3 – Agencies consulted 2013-14
- Attachment 4 – Letters and Scripts
- Attachment 5 – Informed Consent Brochures
- Attachment 6 – ERB Approval
- Attachment 7 – Laboratory Assessments
- Attachment 8 – MEC Data Collection Forms and NHANES Questionnaires
- Attachment 9 – Report of Findings
- Attachment 10 –Special Study/Pretest
- Attachment 11 - Pubertal Maturation Self-Assessment Informational Flyers