

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

OMB No. 0920-0237

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B. Collection of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

The sample design of 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.

DHANES staff met with staff at the Asian Pacific Islander American Health Forum (APIAHF) on January 27, 2010 to discuss increasing the number of API Americans included in the NHANES sample beginning in the 2011-2012 survey. The APIAHF had written a letter to OMB in response to solicitation of comments related to the request for clearance of the 2009-2010 NHANES. APIAHF was extremely supportive of NHANES, but encouraged the expansion of the NHANES sample in order to produce statistics on the API American population. DHANES, along with our data collection contractor, have developed a sampling plan to do that without dropping any of the currently oversampled populations in NHANES. In order to substantially increase the participation of API Americans, significant advance work will be necessary including developing targeted outreach materials; translations of brochures, questionnaires, consent forms, etc.; obtaining endorsements from national and local organizations influential in the API American communities; conducting cultural competency training with our field staff; identifying competent translation services in the communities NHANES surveys, and more.

The APIAHF has agreed to work with us to develop materials, and identify the resources needed to make this a successful expansion of the NHANES sample and produce some of the first national prevalence estimates of the health of API Americans.

Our goal is to increase willingness of the Asian American population to participate in NHANES as well as to improve visibility of NHANES in the Asian American communities. Our strategy entails working closely with the APIAHF on these particular tasks:

- a. Translating and reviewing informative brochure and survey materials such as consent forms, confidentiality brochure, and the NHANES advance letter in numerous Asian languages
- b. Creating new documents such as glossary of medical terms and one-page outreach flyer
- c. Obtaining endorsement signatures from national Asian organizations for NHANES
- d. Developing strategies to ensure that NHANES maximizes resources through media outlets
- e. Helping to recruit interview staff who are proficient in Asian languages
- f. Strengthening relationship with the Asian community through networking, meetings, language schools at the county level

Table 1 shows the sampling domains for NHANES. These domains represent the analytic subpopulations of interest, i.e., there is a need to make estimates of health characteristics within these subpopulations. For NHANES 2011-2014, there are 87 sampling domains defined by race/ethnicity, gender, age, and, for the white/other

NHANES – Supporting Statement – Section B.

domains, low income status (i.e., households in which the household income is below 130% of the poverty level).

Table 1 shows the annual and cumulative estimates of the target sample sizes by analytic 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 2011-2014 is to average 76 percent. In NHANES 2005, 2006, 2007, 2008, and 2009, the examination response rates were 78, 77, 74, 74 and 79 percent, respectively.

Table 1: Projected population size, number of sampled persons, and projected response rates for NHANES 2011-2014						
in 60 PSUs by age, race/ethnicity, income, and gender						
			Projected population average over years 2011-2014 ¹	Total sample	Estimated exam response rate	Target number of exams for 2011-2014
Black, non-Hispanic	M&F	0-11 mos.	674,174	261	84%	220
		1-2 yrs.	1,330,381	423	87%	368
		3-5 yrs.	1,942,242	437	84%	368
	M	6-11 yrs.	1,918,151	433	85%	368
		12-19 yrs.	2,529,339	445	83%	368
		20-39 yrs.	5,280,450	534	73%	392
		40-49 yrs.	2,321,704	281	70%	196
		50-59 yrs.	2,232,042	295	66%	196
		60+ yrs.	2,150,364	586	67%	392
	F	6-11 yrs.	1,867,886	447	82%	368
		12-19 yrs.	2,543,160	440	84%	368
		20-39 yrs.	6,110,951	493	80%	392
		40-49 yrs.	2,818,348	277	71%	196
		50-59 yrs.	2,706,781	317	62%	196
		60+ yrs.	3,173,942	616	64%	392
Total Black, non-Hispanic			39,599,914	6,286	76%	4,780
Hispanic	M&F	0-11 mos.	1,089,092	415	89%	368
		1-2 yrs.	2,141,008	420	88%	368
		3-5 yrs.	3,139,421	459	80%	368
	M	6-11 yrs.	3,132,004	451	82%	368
		12-19 yrs.	3,897,529	445	83%	368
		20-39 yrs.	8,407,598	529	70%	368
		40-49 yrs.	3,562,104	257	72%	184

NHANES – Supporting Statement – Section B.

		50-59 yrs.	2,391,547	243	76%	184
		60+ yrs.	2,159,484	581	64%	372
	F	6-11 yrs.	3,035,955	447	82%	368
		12-19 yrs.	3,701,758	445	83%	368
		20-39 yrs.	7,923,139	455	81%	368
		40-49 yrs.	3,333,519	238	77%	184
		50-59 yrs.	2,464,093	247	74%	184
		60+ yrs.	2,700,912	590	63%	372
Total Hispanic			53,079,163	6,223	77%	4,792
Non-Hispanic, non-Black Asian	M&F	0-11 mos.	233,012	88	77%	68
		1-2 yrs.	471,178	183	77%	140
		3-5 yrs.	706,885	275	66%	180
	M	6-11 yrs.	697,062	270	76%	204
		12-19 yrs.	877,572	342	68%	232
		20-39 yrs.	2,417,584	411	74%	304
		40-49 yrs.	1,255,497	304	51%	156
		50-59 yrs.	944,805	251	62%	156
		60+ yrs.	1,057,490	412	59%	244
	F	6-11 yrs.	684,332	268	76%	204
		12-19 yrs.	895,244	323	72%	232
		20-39 yrs.	2,703,143	489	62%	304
		40-49 yrs.	1,375,901	312	50%	156
		50-59 yrs.	1,105,732	269	58%	156
		60+ yrs.	1,375,374	536	54%	288
Total non-Hispanic, non-black Asian			16,800,812	4,732	64%	3,024
White/Other Low Income	M&F	0-11 mos.	391,169	137	91%	124
		1-2 yrs.	887,794	138	90%	124
		3-5 yrs.	1,168,203	146	85%	124
	M	6-11 yrs.	1,093,558	150	83%	124
		12-19 yrs.	1,278,739	143	87%	124
		20-29 yrs.	1,717,072	157	82%	128
		30-39 yrs.	920,739	156	82%	128
		40-49 yrs.	1,169,242	155	83%	128
		50-59 yrs.	1,251,108	163	79%	128
		60-69 yrs.	1,041,702	155	83%	128
		70-79 yrs.	630,528	170	75%	128
		80+ yrs.	377,839	146	58%	84
	F	6-11 yrs.	983,467	142	87%	124
		12-19 yrs.	1,354,427	142	88%	124
		20-29 yrs.	2,514,596	159	80%	128
		30-39 yrs.	1,485,968	148	86%	128
		40-49 yrs.	1,370,541	145	88%	128
		50-59 yrs.	1,426,091	160	80%	128
		60-69 yrs.	1,621,617	162	79%	128
		70-79 yrs.	1,270,799	173	74%	128
		80+ yrs.	1,259,338	239	54%	128
Total White/Other Low Income			25,214,539	3,286	80%	2,616

NHANES – Supporting Statement – Section B.

White/Other	M&F	0-11 mos.	1,969,723	292	78%	228
Not Low Income		1-2 yrs.	3,824,644	295	77%	228
		3-5 yrs.	5,879,919	295	77%	228
	M	6-11 yrs.	6,142,447	311	73%	228
		12-19 yrs.	8,456,481	286	80%	228
		20-29 yrs.	11,308,888	325	70%	228
		30-39 yrs.	11,180,561	368	62%	228
		40-49 yrs.	12,432,334	356	64%	228
		50-59 yrs.	14,052,788	342	67%	228
		60-69 yrs.	10,659,189	344	66%	228
		70-79 yrs.	5,616,501	338	67%	228
		80+ yrs.	3,096,878	402	57%	228
	F	6-11 yrs.	5,906,145	305	75%	228
		12-19 yrs.	7,985,401	289	79%	228
		20-29 yrs.	10,452,963	309	74%	228
		30-39 yrs.	10,778,324	345	66%	228
		40-49 yrs.	12,442,842	317	72%	228
		50-59 yrs.	14,378,358	320	71%	228
		60-69 yrs.	10,945,786	363	63%	228
		70-79 yrs.	6,110,217	370	62%	228
		80+ yrs.	4,051,299	454	50%	228
Total White/Other not Low Income			177,671,687	7,024	68%	4,788
Total White/Other			202,886,225	10,310	72%	7,404
TOTAL			312,366,116	27,550	73%	20,000
¹ Population of interest is the civilian noninstitutionalized population in the 50 United States.						

2. Procedures for the Collection of Information

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.

NHANES – Supporting Statement – Section B.

After the listing procedure, which identifies households to be potentially included in NHANES, a pre-Advance Letter postcard and an Advance Letter (Attachment 4) 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. 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 confidentiality (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 (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 9. The Family Relationship Questionnaire is administered first, followed by the Sample Participant (SP) and Family questionnaires. The Sample Participant and Family Questionnaires are occasionally tape recorded for quality control purposes. If the interview is selected for taping a box is checked on the interview consent form indicating signed consent. Additionally, verbal consent is recorded on the audio-tape at the beginning of the tape. At the end of the interview the participant is also offered the option to be given the tape to dispose of. This offer and response are also on the audiotape.

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 as well as reimbursement for transportation expenses and childcare, if necessary.

Participants arrive at the MEC, where the Coordinator (receptionist) greets them and

NHANES – Supporting Statement – Section B.

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 (two of whom are radiological technicians), one phlebotomist, two interviewers, a dentist and a facility equipment specialist.

The examination data collection forms are in [Attachment 9](#). 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 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 10](#).

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.

Participants 6 and older will be asked to wear a physical activity monitor (PAM) for one week, after their MEC exam. The device is worn on the wrist and resembles a wrist watch in size. Because it is waterproof, it will not need to be removed. In addition to monitoring physical activity, this new device will also collect data on patterns of sleep.

A second urine specimen will be collected at home by participants 6 and older, after their MEC examination. Instructions for collecting the second urine specimen will be reviewed at the MEC and the participant will be given the container and a mailer to send it directly to the NHANES contract lab measuring urine albumin.

Six months after the examination, participants ages 6 and older who had a positive serology test for hepatitis C infection are contacted by telephone for a brief follow-up

interview.

Sample Design

Beginning in 2011 some changes are being made to the domains being oversampled. The primary change is the oversampling of the Asian population. Persons 60 and older, Blacks, Hispanics and the low income 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 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 (PSU) (single counties); second: segments within PSU (a block or group of blocks containing a cluster of households); third: households within segments; and fourth: participants within households.

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 boundary 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 (10,000 persons and 30 PSUs for the years 2011-2012).

Selection of Primary Sampling Units (PSUs)

PSUs for NHANES 2011-2014 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/ethnicity-income categories of interest. For the 2011-2014 sample, these are Hispanics, blacks, Asians, and low-income whites and others.

After assignment of the PSU measure of size, the largest counties in terms of the measure of size are included in the sample with certainty. For 2011-2014, there are six certainty PSUs, one of which comprises three study locations. The remaining non-certainty PSUs are grouped into 13 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 52 noncertainty PSUs for a four year period and a total of 60 study locations for a four year sample.

To form 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 2011-2012 or 2013-2014. The other PSU of the pair is assigned to the other two year period. For each of

the 13 major strata, once the two PSUs of the stratum for 2011-2012 are allocated, a PSU is randomly selected for 2011 or 2012. The two remaining PSUs in each major stratum are assigned to the comparable year in 2013-2014. For example, if B is assigned to 2011, then A is assigned to 2013. If C is assigned to 2012 then D is assigned to 2014. The randomness of both pair-wise selection and annual assignment yields a stratified national sample for the 4 year period 2011-2014; national samples for 2011-2012 and 2013-2014 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 large sampling errors).

Selection of Segments and Households within PSUs

To reduce the high cost of screening, area segments (consisting of groups of blocks within Census tracts) will be stratified by ethnicity within PSU, and households are sampled at variable rates depending on the concentration of the various ethnic groups within the stratum.

The measure of size (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 based on Census 2000 population data. Since within-PSU selection for the 2011-2014 sample will occur on a continual basis beginning in mid-2010 and continuing through mid-2014, data from the 2010 Census will be used to calculate the segment MOS as soon as possible, likely in time for PSUs in the 2012 sample.

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. A modification of a sequential sampling procedure known as Perkins Stop Rule is used to efficiently control the number of persons selected for examination at each PSU.

Selection of Sample Persons within Households

The sample of persons is selected by (1) listing all households within sample segments; (2) selecting a sample of households for screening; (3) subsampling persons within households to obtain the desired sample sizes.

The subdomains are identified in Table 1. Each race/ethnic, 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/ethnicity 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. The screening rates have been designed to minimize the variability in sampling rates among strata but still achieve the desired precision.

NHANES – Supporting Statement – Section B.

Subsampling is needed to achieve the required sample sizes by age, sex, and race/ethnicity. 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 will tell the interviewers which persons are to become sample persons within each household.

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-ethnicity category approximately equal to independent control totals from the Current Population Survey (CPS) conducted by the U.S. Bureau of the Census. The population controls will be derived at the midpoint of each survey year. To analyze multiple year samples, sampling weights can either be averaged over the sampled years used or can be readjusted to population controls for the midpoint of the combined years.

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 (primary sampling unit) 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, Inc.), SAS Survey Procedure (SAS Institute), and STATA (StataCorp).

Analytic guidelines are provided on the NHANES website (http://www.cdc.gov/nchs/nhanes/nhanes2003-2004/analytical_guidelines.htm) to inform users of the limitations of the data. These are updated and expanded with each data release. "The analytic guidelines are also provided in Attachment 7."

Additionally, NCHS has web-based tutorials (<http://www.cdc.gov/nchs/tutorials>) designed to meet growing demands of NHANES data users and promote broader & 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. (Continuing Medical Education credit, Continuing Nursing

NHANES – Supporting Statement – Section B.

Education credit, or Continuing Education Units can be earned for the courses in the Continuous NHANES Web tutorial.) Tutorials for previous NHANES (I, II and III) have subsequently been released.

New modules are currently being developed on analyzing environmental chemical data and in addition to the existing Dietary Tutorial an Advanced Dietary Tutorial is being developed in collaboration with NCI and the Agricultural Research Service of USDA.

Precision

As a guideline in evaluating the reliability of precision of estimates derived from NHANES surveys, a relative standard error or coefficient of variation (CV) of 30 percent or less was used.

Many domain specific analyses will not be feasible after two years and will require collapsing domains to increase the domain size and produce reliable estimates. However, after four years are completed more detailed estimates will become possible. The sample sizes in many sampling domains will not be sufficient to meet the NHANES precision requirements after only 2 years of data collection. Therefore, many of the NHANES analyses will require at least four years of data to produce reliable national estimates. Because each two-year sample is nationally representative, samples may be aggregated to produce national estimates for combinations of 4 or 6 years. For some rare health conditions, six years of data may be required to produce estimates with an adequate precision and reliability.

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 primary sampling units 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, strata and SPs are done prior to the survey to eliminate bias in the selection process. Although there is no formal quality control plan for the sampling design, various verification checks will be made to ensure the quality and validity of the procedures performed.

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 Attachment 9.

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 are, a mother with childcare needs, a person who refuses due to scheduling issues or time restraints, 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
- Payment for transportation/arrangement 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
- Videotapes for TV stations
- Population specific brochures about the survey
- Multimedia presentation on interviewers' tablet computers
- Evaluative studies of response where appropriate

NHANES – Supporting Statement – Section B.

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 attempts by the interviewer to conduct the screener or an interview. After the first unsuccessful attempt, 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 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 are working 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.
- Increased interviewer training to focus on refusal conversion at both mid year and annual trainings. Sensitivity training for all field and home office staff is planned for the 2010 mid-year retraining on working with Asian Americans. This will be repeated at the January 2011 training and will be expanded to include the other minority groups (blacks and Hispanics) that we already oversample.
- 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 a 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.
- Increased field supervisor training on reminder calls and other contact with sample persons (i.e., even a simple call dealing with how to get to the MEC) by

NHANES – Supporting Statement – Section B.

supervisors with the idea that any time one speaks to a household one has an opportunity to promote NHANES. A pilot test is underway to test the use of text messaging as a reminder mechanism in addition to phone calls.

- 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 PSUs.
- 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.

4. Tests of Procedures or Methods to be Undertaken

Many components of the NHANES field operations have been implemented in past 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. These questions have been tested in the NCHS Questionnaire Design Research Laboratory (QDRL) 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 (for example, the Cardiovascular Health Study). 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 pilot testing of new procedures concurrent to NHANES data collection will be required. 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 pilot testing. Pilot testing must be concurrent to the ongoing data collection within the framework of the survey. 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

NHANES – Supporting Statement – Section B.

adequacy of facility and supplies. NCHS staff, Westat 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 sample design is changed to include an oversample in a new target group. In such an instance, there would not already be enough respondents in the new oversampled group among existing survey respondents. As a result, paid volunteers from within the new target group would be specifically recruited to ensure that components being tested were feasible for this group as well.

DHANES staff has begun a more in-depth process of evaluating all proposed NHANES questionnaire material, even those previously tested or validated. This evaluation process includes validation projects as well as cognitive and/or pilot testing. For 2011-12, the specific sections being evaluated are muscle injury/pain, chemosensory and selected health behavior questions.

Pilot and Methodological Testing for NHANES 2011-2012

A feasibility study for pubertal maturation self-assessment has been completed. It was conducted from March through August 2009. The report for this study is in Attachment 12a. Several other protocols are being tested to be included in the 2011-2012 NHANES, after Ethics Review Board and OMB approval. As noted above, testing will occur within the current data collection whenever possible. When necessary, testing among paid volunteers will also be included. Informed consent will be modified as appropriate for the pilot or methodological test. . If the pilot or methodological test is deemed successful it will be included in the NHANES 2011-12 subject to OMB and ERB approval. DHANES plans pilot and methodological tests only for content fully expected to be successfully implemented on the NHANES survey. A report of each test is produced after completion of the pilot or methodological project.

The methodological studies and pilot tests planned include the following (for which OMB approval has been received):

Pre examination methodological data collection

- i. Text Messaging Pilot Study (ages 12+)

Pilot tests of 2011-12 Examination Center Components:

- ii. Cognitive Functioning (ages 60+)
- iii. Oral Health (ages 2+)
- iv. Pubertal Maturation (ages 8-19)
- v. Muscle Strength (ages 6+)
- vi. Sagittal Abdominal Diameter (SAD) (ages 8+)
- vii. Creatinine Phosphokinase (ages 12+)
- viii. Chemosensory Variation and Impairment (ages 40+)

Post examination methodological data collection:

- ix. Physical Activity Monitor (PAM) (ages 6+)
- x. 24 Hour Urine Sodium Validation Study (ages 20-79)

The Division of Health and Nutrition Examination Surveys (DHANES) anticipates that new technology will be adopted during future data collection activities. NCHS staff

NHANES – Supporting Statement – Section B.

design, plan, implement and evaluate numerous methodology projects to evaluate new technology proposed for use in NHANES. For example, new questionnaire modules and examination component protocols are often pre-tested in-house and in the field prior to full survey implementation. This process may include cognitive testing of questions as well as pilot testing of components in the actual NHANES environment. Past experience has shown that one to three years of preparatory work may be required to fully test and prepare a new NHANES examination component for the survey. New equipment must be installed, calibrated, and tested; software must be installed and tested; database variables and data processing procedures must be developed and documented; data security provisions must be developed, tested, and approved; and training manuals, staff training, and quality control procedures must be developed.

The survey expects to continue conducting pilot studies for future cycles of continuous NHANES. During 2011-2012, pilot studies will be conducted to prepare for implementation during NHANES 2013-2014. Plans for future pilot studies have not been finalized. One methodologic study for future consideration is a 24 hour urine sodium study.

Sodium consumption in the US population is well above recommended limits. It is widely believed that the high sodium intake may be partially responsible for the high prevalence of hypertension in the US population. Efforts on many fronts in the public health community are targeting a reduction in sodium in the food supply. NHANES monitors the dietary intake of the US but dietary recalls are considered inadequate measures of dietary sodium intake at this time. Urinary excretion better characterizes sodium consumption but is extremely variable. Several studies have concluded that casual urine samples correlate sufficiently with 24 hour urine collections to allow for monitoring population intake of sodium. NHANES currently collects two urine specimens under conditions more rigid than 'casual'. One is a timed urine collection and the second is the first morning void. NHANES is considering monitoring population sodium intake by adding a 24 hour urine collection to its current urine protocol.

A change package would be submitted to OMB before undertaking any methodological and/or pilot studies.

A Community HANES has been an area of interest for a number of years. If the opportunity arises, we would like to undertake methodological and other studies under this approval. This request permits NCHS the option to plan and test a Community HANES (C-HANES) project. C-HANES is a survey mechanism to address health status issues of defined populations (e.g., race/ethnic groups and/or small geographic areas) for which the standard, cross-sectional NHANES is inappropriate or infeasible. The age groups surveyed may be broad or may be restricted to certain subgroups, depending on the community's needs. C-HANES should provide rapid access to health data. Typically, the time elapsed from the start of a project to data dissemination will be less than two years. The C-HANES can also provide a means to bring an examination center to the sample person through the use of smaller mobile examination units than the MECs used in the main survey.

The C-HANES interview and examination components and their protocols will be similar to those of previous NHANES. However, new components and new data collection methods may be added depending on the objectives of the survey and the population surveyed. The data collection system will include some or all of the following: interviews

NHANES – Supporting Statement – Section B.

in the home; interviews at the examination center; physiological, medical, and dental examinations; and biological specimen collection. Space, time, and resources will be, as usual, the limiting factors for what can be done in the survey and where.

CDC is including burden hours to accommodate a C-HANES project involving up to 4,000 participants (Section 12, Table 1, line 2). This project would include an interview and examination component similar to the current NHANES, but no post-examination components. Pilot tests or methodological studies to develop new NHANES components are also included in the line 2 burden. OMB would be notified of any such projects through a change package.

Nonresponse Investigation

Nonresponse investigations under DHHS task order contracts or other contract mechanisms may be necessary should nonresponse rates make that advisable. Reliable estimates for subpopulations of interest would be impaired if nonresponse in those subpopulations were unacceptably high. Although NHANES uses many time-consuming and costly mechanisms to increase response rates, separate scientific investigations of the causes of nonresponse and possible remedies may be needed and approval for such options is hereby requested. Details of any such investigations that involve public participation will be submitted to OMB as required in the terms of clearance.

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:

Lester R. Curtin, Ph.D.
Mathematical Statistician
Division of Health and Nutrition Examination Surveys
National Center for Health Statistics
Centers for Disease Control and Prevention
Phone: 301-458-4172

2) The following person is responsible data collection activities:

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

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

Clifford L. Johnson
Director, Division of Health and Nutrition Examination Surveys
National Center for Health Statistics
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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 2011-12

Attachment 4 – Letters and Scripts

Attachment 5 – Informed Consent Brochures

Attachment 6 – ERB Approval

Attachment 7 – Analytic Guidelines

Attachment 8 – Laboratory Component

Attachment 9 – MEC Data Collection Forms and NHANES Questionnaires

Attachment 10 – Report of Findings

Attachment 11 –Special Study/Pretest

Attachment 12a - Pubertal Maturation Self-Assessment Feasibility Study

Attachment 12b - Pubertal Maturation Self-Assessment Informational Flyers