

**Supporting Statement B**

**National Health and Nutrition Examination Survey**

**OMB No. 0920-0950**

(Expires November 30, 2015)

**Revision**

**Contact Information:**

Vicki Burt  
National Center for Health Statistics (CDC)  
Chief, Planning Branch  
National Health and Nutrition Examination Survey  
3311 Toledo Road, Room 4211  
Hyattsville, MD 20782

Email: [vburt@cdc.gov](mailto:vburt@cdc.gov)

Phone: 301-458-4127

FAX: 301-458-4028

**October 28, 2013**

Supporting Statement B (Revision)  
National Health and Nutrition Examination Survey (0920-0950)

B. Collection of Information Employing Statistical Methods

The statements below refer to the request to conduct a 24-hour urine collection in NHANES. Below this additional data is the complete Supporting Statement B for the data collection approved on November 28, 2012. There have been no changes to that document.

1. Respondent Universe and Sampling Methods

The 24-hour urine component will be conducted with a random half sample of NHANES participants, ages 20-69 years, who were examined in the mobile exam center (MEC). NHANES survey statisticians estimate that there will be 2,640 examined sample participants aged 20-69 in the 2014 NHANES. The selection of the one half random sample of NHANES examinees for the 24-hour urine will be done using the existing NHANES subsampling mechanism. That mechanism is based on dividing the Sample Person ID by 20 and selecting one-half of the integer remainders between 0 and 18. Participants who have a Sample Person ID with one of those remainders will be asked to participate in the 24-hour urine collection. The remainders for the 24-hour subsample collection are: 1, 4, 5, 6, 7, 9, 10, 11, 13, and 18. Participants will be asked to collect urine samples over a 24-hour period.

One-half of the participants who successfully complete the first collection will be invited to collect a second 24-hour urine. The selection of participants to do the second 24-hour urine collection will also be done using the NHANES subsampling mechanism. The mechanism is based on dividing the Sample Person ID by 20. Participants with remainders 1, 5, 10, 11, and 18 will be asked to collect a second 24-hour urine sample.

2. Procedures for the Collection of Information

Collection Procedures

The 24-hour urine collection is a post-examination component of NHANES. Informed consent for the NHANES examination includes post examination components including the 24-hour urine. At the time consent is obtained the participant is given a 'Health Measurements List' that contains a list of NHANES examination content and what ages will get various content components or laboratory tests. The 24-hour urine will be

included in the section of this list subtitled “After your visit to the NHANES mobile center”. The statement describing it will say, “Select persons (ages 20-69) will be asked to collect their urine for 24 hours”. The revised Health Measurements List and the consent for the 24-hour urine collection are in Attachment 14. For the first collection, these two sentences are added: “Your participation is voluntary” and “May I schedule your two visits?” (the second visit is to complete the collection and drop off the collected urine). For the second 24-hour urine request these two sentences are added: “Your participation is voluntary” and “May I make an appointment for you to repeat the 24-hour urine collection?” The exact placement of these sentences in the protocol for explaining the collections and making the appointment is in the ERB protocol in Attachment 14, pp 12 and 13.

Participants will be scheduled to return to the Urine Component MEC (UMEC). They will receive a phone call to remind them of their appointment to start the urine collection (unless their start date is the following day). If a participant does not have a phone where he/she can be reached, an NHANES staff member will make a personal visit to remind them of their appointment to start urine collection.

A flowchart in Figure 1 (page 5) describes the 24-hour urine collection process. Upon arriving for their appointment, a urine collection kit will be given to the participant to use for collecting urine samples over a 24-hour period. The kit will contain instructions on how to collect and return the urine specimen. To increase week day collections, a random six-tenths of 24-hour urine participants will be asked to collect on a week day. If the participant indicates it is impossible for them to collect during the assigned interval they will not be excluded from participation. They will be allowed to schedule during the alternative time interval. Participants will be asked to end their urine collection in the UMEC. When scheduling them to return their urine sample, participants will be asked to void at the UMEC to end the 24-hour collection. If not possible, they will be asked to bring the urine samples back within 24-48 hours of the start of collection. A set of completion questions will be used to assess the completeness of the urine collection (Attachment 14).

A complete urine collection is judged by urine volume, collection time, and responses to the Completion Questionnaire (Attachment 14, page 31).

The urine specimen will be considered “incomplete” if:

- The start and end time of the collection was not recorded and cannot be ascertained
- The length of collection time is <22 hours
- The total volume of urine is less than 400 ml
- A female participant was menstruating during the urine collection (Item UCQ001)

on Completion Questionnaire)

- More than a few drops of urine were missed during collection (Items UCQ002-UCQ008 on Completion Questionnaire)

All urine specimens collected over a period of at least 22 hours which meet other criteria for completeness, will be processed (weighed, aliquoted and shipped). NCHS will determine whether specimens collected over a 26+ hour time frame will be included in the analytic sample.

One-half of the participants who successfully complete the first collection will be invited to collect a second 24-hour urine. If the participant agrees, the second 24-hour urine collection will be scheduled 3-10 days later, but not on the same day of the week as the first 24-hour urine collection. Dietary intake varies significantly from day to day not just from week day to weekend day. Therefore to better characterize individuals intake it is desirable to have the two 24-hour urines on different days of the week. The day of the week assigned will not be based on the weekend/week day randomization above and will not be an absolute requirement of participation.

An incentive of \$100 will be given to the participant at the end of both the first and second urine collections. This is consistent with the incentive offered in the pilot.

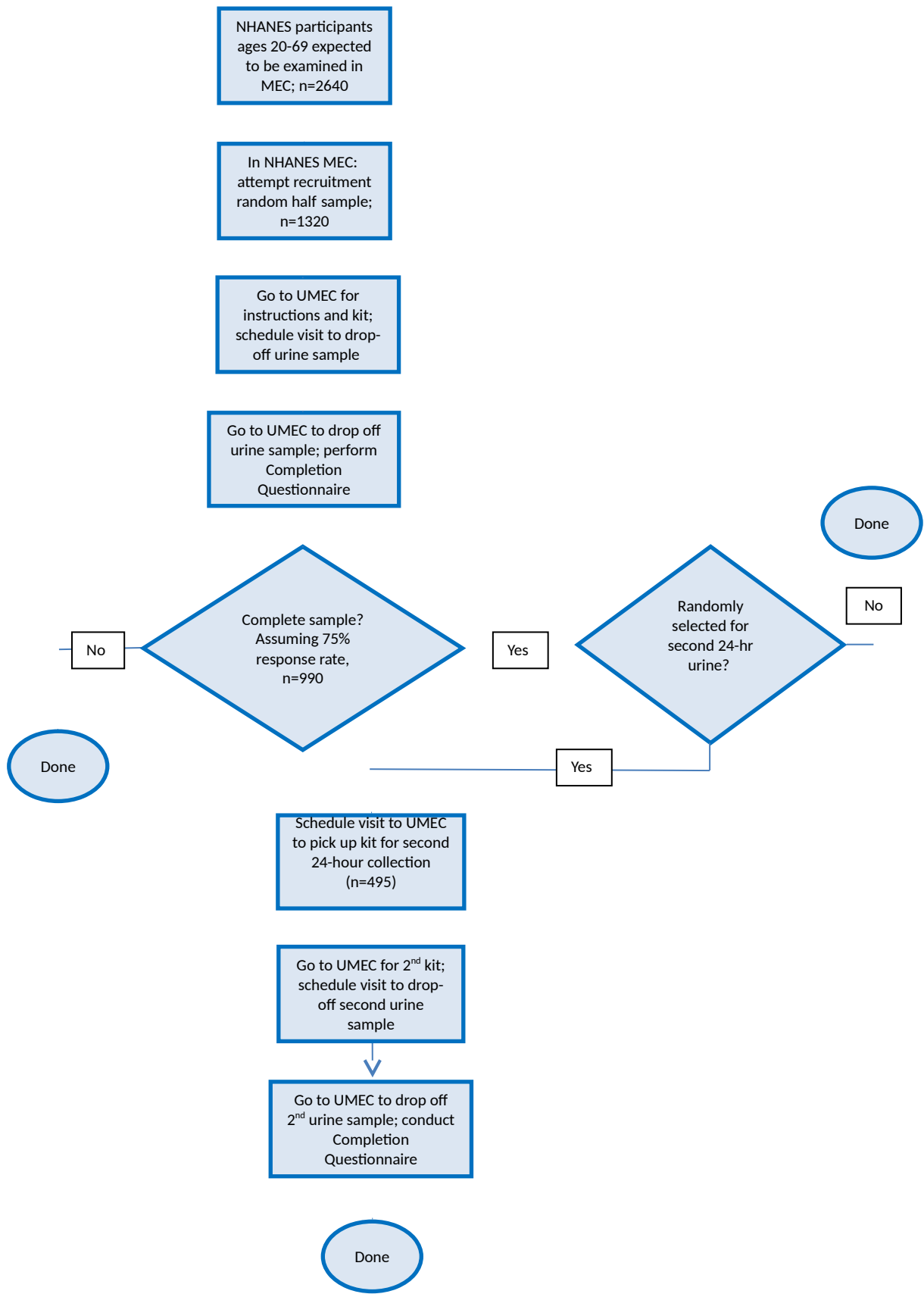


Figure 1. 24-Hour Urine Collection Flow Chart

#### 4. Tests of Procedures or Methods to be Undertaken

A 24-hour urine pilot study was conducted as part of the NHANES to test the feasibility of implementing a 24-hour urine collection in NHANES 2014. The pilot study was conducted March - June 2013 in three NHANES locations, including suburban, urban and rural populations.

Two-hundred and eighty-two adults aged 20-69 years were sampled for the pilot. Of those who were sampled, 75% (n=212) successfully completed one 24-hour urine collection. A random half-sample of those 212 were asked to collect another 24-hour urine. Ninety-two or 85% successfully completed a second 24-hour urine collection. The criteria outlined in the earlier OMB pilot submission indicated that the pilot would be considered successful if 70% of eligible participants agreed to participate and successfully completed the first 24-hour urine collection and if 70% of those asked to collect a second 24-hour urine sample did so successfully. Based on the pre-specified response rate criteria, the pilot was considered a success. A detailed report of the pilot test is included in Attachment 13.

#### Attachments

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 – Analytic Guidelines

Attachment 8 – Laboratory Assessments

Attachment 9 – MEC Data Collection Forms and NHANES Questionnaires

Attachment 10 – Report of Findings

Attachment 11 –Special Study/Pretest

Attachment 12 - Pubertal Maturation Self-Assessment Informational Flyers

Attachment 13 – Results of 24-Hour Urine Pilot Study

Attachment 14 – 24-Hour Urine Collection Protocol

Attachment 15a – Federal Register Notice – 24-hour Urine Revision

Attachment 15b –Federal Register Notice Responses – 24-hour Urine Revision

The original Supporting Statement B - National Health and Nutrition Examination Survey, approved on November 28, 2012, is below.

## 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.

It has become increasingly difficult to complete all the screening planned for the NHANES 2011-2014 sample due to such factors as more locked buildings in the sample and the need to have more interpreters accompany interviewers to complete screening. The increased labor to complete screeners competes with the interviewers' need to interview and schedule examinations, given the limited amount of time field staff are present in each survey location. Because of this in 2013-14 we are decreasing the screening amounts by about 30% to free up more interviewer time for these competing activities. This may result in small decreases in sample yield in selected domains that require a high level of screening. It may not decrease expected yield in other domains. For example, when we planned the 2011-14 sample design, the analytic domain for black children ages 1-2 was considered the rarest; therefore, it would require the highest number of screeners. Our experience in 2011-12 to date has indicated that we will get more than our targeted sample size. Therefore, we don't expect a decrease in analytic potential for this age group because of the 30% reduction in screening.

To maintain our target number of examinations at 5,000 per year, more examinations will be redistributed to certain analytic domains, such as Hispanics and non-low income whites/others. This is needed to meet the total target sample yield of 20,000 examinations for NHANES 2011-2014. This redistribution will slightly decrease the sample yield in the Hispanic subgroup, bring the distribution of the non-low income whites/others closer to the expected level, and have an Asian sample that comprises 13% of the expected sample rather than 14%. Some Hispanic and all white/other analytic domains will have additional exams in the 2013 and 2014 sample to increase the sample yield in these groups.

Table 1 shows the sampling domains for NHANES. These domains represent the sampling subpopulations of interest. For NHANES 2011-2014, 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. The Asian oversample that began in 2011-2012 will be continued for 2013-2014.

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. Given the sample design changes in 2011-2014, particularly the addition of the Asian oversample, the goal for the overall examination response rate for NHANES 2011-2014 is 73 percent, which is slightly lower than past years. In NHANES 2009, 2010 and 2011, the



examination response rates were 78, 77 and 72 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 and Hispanic origin, income, and gender						
			Projected population average over years 2011-2014 <sup>1</sup>	Total sample	Estimated exam response rate	Target number of exams for 2011-2014
Black, non-Hispanic	M&F	< 1 year	674,174	231	84%	194
		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	6,256	76%	4,754
Hispanic	M&F	<1 year	1,089,092	368	89%	326
		1-2 yrs.	2,141,008	425	88%	372
		3-5 yrs.	3,139,421	467	80%	374
	M	6-11 yrs.	3,132,004	458	82%	374
		12-19 yrs.	3,897,529	454	83%	376
		20-39 yrs.	8,407,598	550	70%	382
		40-49 yrs.	3,562,104	277	72%	198
		50-59 yrs.	2,391,547	257	76%	194
		60+ yrs.	2,159,484	588	64%	376
	F	6-11 yrs.	3,035,955	454	82%	374
		12-19 yrs.	3,701,758	455	83%	376
		20-39 yrs.	7,923,139	475	81%	384
		40-49 yrs.	3,333,519	256	77%	198
		50-59 yrs.	2,464,093	261	74%	194
		60+ yrs.	2,700,912	596	63%	376
Total Hispanic			53,079,163	6,338	77%	4,874

Table 1: Projected population size, number of sampled persons, and projected response rates for NHANES 2011-2014 in 60 PSUs by age, race and Hispanic origin, income, and gender

Non-Hispanic, non-Black Asian	M&F	< 1 year	233,012	78	77%	60
		1-2 yrs.	471,178	162	77%	124
		3-5 yrs.	706,885	241	66%	158
	M	6-11 yrs.	697,062	238	76%	180
		12-19 yrs.	877,572	301	68%	204
		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	361	59%	214
	F	6-11 yrs.	684,332	234	76%	178
		12-19 yrs.	895,244	292	72%	210
		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	469	54%	252
Total non-Hispanic, non-black Asian			16,800,812	4,411	64%	2,812
Non-Hispanic White/Other	M&F	< 1 year	391,169	126	91%	114
Low Income		1-2 yrs.	887,794	140	90%	126
		3-5 yrs.	1,168,203	148	85%	126
	M	6-11 yrs.	1,093,558	152	83%	126
		12-19 yrs.	1,278,739	145	87%	126
		20-29 yrs.	1,717,072	162	82%	132
		30-39 yrs.	920,739	159	82%	130
		40-49 yrs.	1,169,242	157	83%	130
		50-59 yrs.	1,251,108	165	79%	130
		60-69 yrs.	1,041,702	157	83%	130
		70-79 yrs.	630,528	173	75%	130
		80+ yrs.	377,839	128	58%	74
	F	6-11 yrs.	983,467	144	87%	126
		12-19 yrs.	1,354,427	146	88%	128
		20-29 yrs.	2,514,596	167	80%	134
		30-39 yrs.	1,485,968	153	86%	132
		40-49 yrs.	1,370,541	149	88%	132
		50-59 yrs.	1,426,091	163	80%	130
		60-69 yrs.	1,621,617	167	79%	132
		70-79 yrs.	1,270,799	176	74%	130
		80+ yrs.	1,259,338	243	54%	130
Total non-Hispanic White/Other Low Income			25,214,539	3,321	80%	2,648
Non-Hispanic White/Other	M&F	< 1 year	1,969,723	300	78%	234
Not Low Income		1-2 yrs.	3,824,644	308	77%	238
		3-5 yrs.	5,879,919	316	77%	244

Table 1: Projected population size, number of sampled persons, and projected response rates for NHANES 2011-2014 in 60 PSUs by age, race and Hispanic origin, income, and gender

	M	6-11 yrs.	6,142,447	333	73%	244
		12-19 yrs.	8,456,481	316	80%	252
		20-29 yrs.	11,308,888	364	70%	256
		30-39 yrs.	11,180,561	407	62%	252
		40-49 yrs.	12,432,334	399	64%	256
		50-59 yrs.	14,052,788	390	67%	260
		60-69 yrs.	10,659,189	381	66%	252
		70-79 yrs.	5,616,501	359	67%	242
		80+ yrs.	3,096,878	412	57%	234
	F	6-11 yrs.	5,906,145	326	75%	244
		12-19 yrs.	7,985,401	317	79%	250
		20-29 yrs.	10,452,963	344	74%	254
		30-39 yrs.	10,778,324	381	66%	252
		40-49 yrs.	12,442,842	361	72%	260
		50-59 yrs.	14,378,358	370	71%	264
		60-69 yrs.	10,945,786	401	63%	252
		70-79 yrs.	6,110,217	392	62%	242
		80+ yrs.	4,051,299	470	50%	236
Total non-Hispanic White/Other Not Low Income			177,671,687	7,648	68%	5,218
Total non-Hispanic White/Other			202,886,225	10,969	72%	7,866
TOTAL			312,366,116	27,974	73%	20,306

<sup>1</sup> Population of interest is the civilian noninstitutionalized population in the 50 United States.

## 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 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 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 recorded for quality control purposes. Verbal consent is 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 (2<sup>nd</sup> dietary recall by phone, return of activity monitor after wearing 7 days, and mailing in home urine collections) 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 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. After successful completion of the second dietary recall on the phone the participant will be remunerated as detailed in Section A.9.

Participants 3 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.

After wearing the PAM for 7 days and mailing it back the participant will be remunerated as detailed in Section A.9

Two urine specimens will be collected at home by participants 20-69, after their MEC examination. Instructions for collecting the additional urine specimens will be reviewed at the MEC and the participant will be given the containers and a mailer to send it directly to the NHANES storage facility.

A pilot test of a 24 hour urine specimen may be collected. A change package will be submitted for approval before undertaking this effort.

### Sample Design

Persons 60 and older, 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 noted above, for the 2013-14 survey we have made a sample design revision to the screening amounts which have been tailored to meet the goals for the analytic domains of the survey and the targeted sample sizes increased in other analytic domains to meet the overall targeted sample yield for NHANES 2011-2014.

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 2013-2014).

### 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 and Hispanic origin - income categories of interest. For the 2011-2014 sample, these are Hispanics, non-Hispanic 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 of the 60 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 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 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 four 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 for 2013 and 2014 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. 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 and; (3) subsampling persons within households 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. The screening rates have been designed to minimize the variability in sampling rates among strata but still achieve the desired precision.

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 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), SAS Survey Procedures (SAS Institute), and STATA (StataCorp).

Analytic guidelines are provided on the NHANES website ([http://www.cdc.gov/nchs/nhanes/nhanes2003-2004/analytical\\_guidelines.htm](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 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. (Continuing Medical Education credit, Continuing Nursing 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.

In recent years, four new NHANES tutorials have been released. They are the NHANES Environmental Chemical Data Tutorial, the NHANES Physical Activity and Cardiovascular Fitness Data Tutorial, the first two courses of the NHANES-Center for Medicare and Medicaid Services Linked Data Tutorial and the final course of the NHANES Dietary Tutorial, Advanced Dietary Analyses, which describes techniques for estimating usual intake of dietary and supplement intake, how dietary intakes vary among individuals, and how individual intakes relate to other factors.

#### Precision

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

The sample sizes in many analytic 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 sample participants 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 is 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 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 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 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 is 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) 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 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.

#### **Pilot Tests for the 2013-14 NHANES**

Several protocols are being tested to include in the 2013-2014 NHANES. The following pilot tests were approved by OMB in May 2012 via a GenIC request (OMB No. 0920-0237). The burden for these tests is already accounted for. One is completed (HPV and the second (Fluorosis) is planned for later in 2012.

- a. NHANES Human Papillomavirus (HPV) Prevalence Among U.S. Men Pilot Study (ages 14-59). This component was pilot tested in July-August 2012. Ninety-six percent of 14-59 year old males who were asked agreed to collect a specimen.
- b. NHANES Dental Fluorosis Imaging Project Feasibility Study (ages 6-19)

If the pilots are successful they will be included in the NHANES 2013-14. A report of each test is produced after completion of the pilot test.

#### **Methodological Studies to be conducted during the approval period for the NHANES 2013-14**

NHANES has several possible methodological or special studies that may occur during 2013-14 They are:

- i. 24 hour dietary recall and/or MEC interview via web-conferencing technology.
- ii. Collection of blood spot specimens on NHANES participants.
- iii. Food Assistance Program Linkage Studies.
- iv. Urine sodium studies
  - i. A 24 hour urine collection on a sample of NHANES participants to evaluate feasibility.

- ii. A separate national sample of as many as 1500 participants who receive a 24 hour urine, dietary recall, venipuncture, blood pressure, height, and weight.

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 conducted in 2013-14 for the 2015-16 NHANES**

The survey expects to continue conducting pilot studies for future cycles of continuous NHANES. During 2013-2014, pilot studies will be conducted to prepare for implementation during NHANES 2015-2016. A non-substantive change package would be submitted to OMB before undertaking any pilot study.

### **Additional Health and Nutrition Examination Studies**

This request permits NCHS the option to plan, test and implement additional Health and Nutrition Examination Studies yet to be proposed. Such a project would be an additional data collection effort focused on a specific age group and/or topic. The interview and/or examination content would be all, or a subset, of the concurrent NHANES content with minor differences. An example might be to sample children such as was done for the NHANES National Youth Fitness Survey (NYFS). (Another example might be a sample of adults that receive an abbreviated examination plus a 24-hour urine in an independent sample from the current NHANES.)

CDC is including burden hours to accommodate such special studies (Attachment 11) involving up to 2,500 participants (Section A12, Table 1, line 2). Pilot tests or methodological studies to develop new NHANES components are also included in the line 2 burden. OMB would be notified of any additional Health and Nutrition Examination Studies through a nonsubstantive change package.

### **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 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:

Lisa Mirel, M.S.  
Statistician  
Division of Health and Nutrition Examination Surveys  
National Center for Health Statistics  
Centers for Disease Control and Prevention  
Phone: 301-458-4745

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: 301-458-127

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 – Analytic Guidelines  
Attachment 8 – Laboratory Assessments  
Attachment 9 – MEC Data Collection Forms and NHANES Questionnaires

Attachment 10 – Report of Findings  
Attachment 11 –Special Study/Pretest  
Attachment 12 - Pubertal Maturation Self-Assessment Informational Flyers