

Section B Supporting Statement for Request for Clearance

National Health And Nutrition Examination Survey

2009-2010

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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.

Table 1, [Attachment 7, part A](#) 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 2007-2010, there are 72 sampling domains defined by race/ethnicity, gender, age, and, for the white/other domains, low income status (i.e., households in which the household income is below 130% of the poverty level).

Table 2, [Attachment 7, part A](#) 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 2007-2010 is to average 76 percent. In NHANES 2003, 2004, 2005, 2006 and 2007, the examination response rates were 75, 76, 78, 77 and 74 percent, respectively.

Table 3, [Attachment 7, part A](#) presents the projected population size, number of sample persons and projected response rates for NHANES in 60 PSUs over a period of four years, by age, race-ethnicity, and gender.

2. Procedures for the Collection of Information

Data Collection Procedures

Westat, Inc will carry out the data collection under contract. Westat's responsibilities 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, 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, 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 (Attachment 9 (p Q-4)), 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 (Attachment 9 (p Q-19)). 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 interview questions appear in Attachment 9 (p Q-19). The Family Relationship Questionnaire is administered first, followed by the Sample Participant (SP) (p Q-32) and Family questionnaires (p Q-206). 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.

The interviewer collects a tap water specimen (see Environmental Chemicals, A. 2. a Perchlorate and VOCs) from the household after the interview is complete for laboratory analysis (Attachment 8, see "water" in matrix). 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

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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 dental hygienist 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 the DR, adult sample persons will also receive the Flexible Consumer Behavior Survey (FCBS) via telephone interview. This survey gathers information about nutrition knowledge, attitudes, and beliefs. The respondent has the option of answering the questions during the same phone call as the DR or scheduling a future phone call. Handcards for the FCBS are provided during the MEC DR.

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 2007 some changes were made to the domains being oversampled. The primary change is the oversampling of the entire Hispanic population instead of just the Mexican American (MA) population, which has been oversampled since 1988. Sufficient numbers of MAs will be retained in the sample design so that trends in the health of MAs can continue to be monitored. Persons 60 and older, Blacks and the low income persons will continue to be oversampled. The oversample of pregnant women and adolescents in the survey from 1999-2006 was discontinued to allow for the oversampling of the Hispanic population. The restrictions imposed by the NHANES examination permit only about 5000 examinations per year. Therefore when a new domain to be oversampled is cycled in, another oversampled domain must cycle out.

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 2009-2010). The target number of participants at each PSU ranges between 235 and 410.

Selection of Primary Sampling Units (PSUs)

PSUs for NHANES 2007-10 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 the 2000 Census data is established for each PSU. The MOS reflects the total population of the county, the percent black and the percent total Hispanic. Previous NHANES oversampled blacks and Mexican Americans. The 2007-2008 cycle of NHANES was the first to include an oversample of all Hispanics.

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 2007-2010, there are five certainty PSUs which comprise eight study locations (due to a few very large PSUs); these are randomly allocated to give two certainty study locations per year. After selection of the certainty PSUs, the remaining non-certainty PSUs are grouped into 13 major strata. The major strata are defined by the four Census regions, metropolitan status (11 metropolitan strata and 2 non-metropolitan strata), and by a race/ethnicity or

income indicator. 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 ordered 4 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 2007-2008 or 2009-2010. 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 2007-2008 are allocated, a PSU is randomly selected for 2007 or 2008. The two remaining PSUs in each major stratum are assigned to the comparable year in 2009-2010. For example, if B is assigned to 2007, then A is assigned to 2009. If C is assigned to 2008 then D is assigned to 2010. The randomness of both pair-wise selection and annual assignment yields a stratified national sample for the 4 year period 2007-2010; national samples for 2007-2008 and 2009-2010 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

In past cycles of NHANES, to reduce the high cost of screening necessary to locate the sample needed for the minority populations, area segments (consisting of block groups/enumeration districts) were stratified by ethnicity within PSU, and households were sampled at variable rates depending on the concentration of the various ethnic groups within the stratum.

An important change for NHANES 2007-2010 is the replacement of Mexican American sampling domains with Hispanic sampling domains. Since Hispanics are more prevalent in the population than Mexican Americans, it is no longer necessary or efficient to stratify segments and sample households at variable rates depending on the ethnic concentrations.

The measure of size (MOS) of a segment is calculated in the same way as for PSUs. 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. 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 for subgroup analyses are described in the next section on precision. 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.

Subsampling is needed to achieve the required sample sizes by age, sex, and race/ethnicity. Experience with NHANES and 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.

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. Table 4, [Attachment 7, part A](#) presents the distribution of the NHANES sample expected for 2009 by sampling domains with 15 PSUs. Table 5, [Attachment 7, part A](#) presents the minimum sample size that is required in each analytic domain to obtain reliable prevalence estimates with a coefficient of variation (CV) of 30 percent and specified design effect. Table 6, [Attachment 7, part A](#) shows the minimum sample size required in an analytic cell to adequately estimate difference in two proportions with a CV of 30 percent and specified design effect.

Table 5, for example, shows that to estimate a prevalence of 10 percent with CV of 30 percent and design effect of 1.5, at least 150 examined persons are required. Thus, after only a single year of data collection, one would need to collapse age or gender or race-ethnic domains to achieve the necessary sample size of 150 examinees (see Table 2, [Attachment 7, part A](#)).

Estimated CVs for expected proportions of 5 percent and 10 percent after two years (n=10,000) and after four years (n=20,000) of data collection are shown in Tables 7a, 7b, 8a and 8b of [Attachment 7, part A](#). Based upon a total of approximately 10,000 examined persons in 30 PSUs after two years and assuming a design effect of 1.5, prevalence statistics of 10 percent will have estimated CVs of less than 30 percent (Table 7a of [Attachment 7, part A](#)) for all specified age, sex, race/ethnicity subdomains except black infants less than 1 year of age, black males ages 40 to 49, black males ages 50 to 59, Hispanic males ages 40 to 49, Hispanic males ages 50 to 59, black females ages 40 to 49, black females ages 50 to 59, Hispanic females ages 40 to 49, and Hispanic females ages 50 to 59. For prevalence of 5 percent or less, estimated CVs are primarily greater than 30 percent (Table 8a of [Attachment 7, part A](#)) for the specified subdomains. Therefore collapsed analytic categories would be required. After

completion of 4 years of data collection, prevalence estimates of 10 percent will result in CVs of 8 to 26 percent (Table 7b of [Attachment 7, part A](#)). After 4 years, prevalence of 5 percent or less will result in CVs of less than 30 percent for all specified age, sex, race/ethnicity subdomains except black infants less than 1 year of age, black males ages 40 to 49, black males ages 50 to 59, Hispanic males ages 40 to 49, Hispanic males ages 50 to 59, black females ages 40 to 49, black females ages 50 to 59, Hispanic females ages 40 to 49, and Hispanic females ages 50 to 59 (Table 8b of [Attachment 7, part A](#)).

These tables demonstrate that 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, as the survey continues and completes additional years of data collection, detailed estimates will become possible. As discussed previously, 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.

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 file. 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, which is available from the Research Triangle Institute, WesVar, which is available from Westat, Inc. and STATA. In addition, SAS and SPSS do a limited set of statistical procedures for survey data.

Analytic guidelines are provided on the NHANES website to inform users of the limitations of the data. These are updated and expanded with each data release. The December 2005 version (last correction, September, 2006) is provided in [Attachment 7, part B](#).

Additionally, in August 2006, NCHS released a web-based tutorial designed to meet growing demands of NHANES data users and promote broader & more proficient use of NHANES data. This self-learning tool, 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.

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.

If any changes in the survey procedures or data collection instruments are desired after receiving clearance, we will submit an OMB Change Form.

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. 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 (A.9)
- 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

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

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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](#).

In addition, since our last submission, the following steps have been taken 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 during the past two years.
- Enhancement of the “obtaining cooperation” portion of the initial interviewer training to include more “real life” practice modules. Training time will be devoted to this topic, beginning in September 2008.
- Increased interviewer training focus on refusal conversion at both mid year and annual trainings.
- Supervisory field staff are encouraged to provide more one on one interviewer training at the field offices on refusal aversion/conversion.
- Listers, who visit PSUs at least four months prior to the opening of stands, are asked to provide more information about every segment they visit so that we can address potential problems as early as possible, especially locked buildings, gated communities, and college campuses.
- 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 supervisors with the idea that any time one speaks to a household one has an opportunity to promote NHANES.
- 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 to obtain 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 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. All pilot/feasibility 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 adequacy of facility and supplies. NCHS staff, Westat development staff and consultants participate in the evaluation effort.

NHANES 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 2009, the specific sections being evaluated are portions of the dietary screener, oral health, inflammatory back pain, arthritis, reactions to race, and flexible consumer behavior survey questions.

Pilot Testing for NHANES 2009-2010

Several protocols were tested to be included in the 2009 NHANES, after Ethics Review Board and OMB approval. As noted above, all occurred within the current data collection and with the informed consent modified as appropriate for the pilot. Some pilot tests are still in progress. If the pilot test is deemed successful it is proposed for inclusion in 2009. NHANES plans pilot tests only for content fully expected to be successfully implemented on the NHANES survey. A report of each pilot becomes available after completion of the pilot.

Pilot Test of Inflammatory Back Pain and Spondyloarthritis

The pilot for the NHANES 2009-10 Arthritis component commenced May 21st, 2008 and will take place at selected 2008 NHANES survey locations through October 2008. Survey participants ages 20-69 years will be eligible to participate. The Arthritis pilot will allow us to assess 1) the performance of the spinal arthritis questionnaire, and 2) the practicality of the arthritis body measures at the NHANES MEC examination sites, and 3) to verify that the arthritis laboratory tests (HLA-B27 testing) can be properly performed by the contract laboratories and properly reported back to the participants prior to fielding the main study in January 2009.

The arthritis questionnaire is designed to measure the prevalence of inflammatory back pain, which is the signature symptom complex characteristic of spinal arthritis (spondyloarthritis). It is anticipated that the arthritis questionnaire will be administered to some 800 participants, the physical examination body measures to about 400 participants, and the arthritis laboratory test to 200 to 400 participants. A report of findings protocol for the arthritis laboratory testing has been developed using standard NHANES guidelines, was approved by the NCHS ERB and will be implemented for the Arthritis pilot laboratory testing.

Pilot Test of Dietary Screener Module

This pilot test is in progress. It began May 21, 2008 and is scheduled to conclude the end of August 2008. This pilot study is designed to evaluate the operational feasibility of the Dietary Screener Module (DTQ) data collection instrument within the context of NHANES 2008. If successful, the module will be part of the National Health and Nutrition Examination Survey (NHANES) in 2009.

The DTQ collects information on participants' intake of fruits and vegetables, fiber, added sugar, dairy/calcium, whole grains, red meat, and processed meat. These were chosen because they are implicated in chronic disease etiology, they are targets of dietary guidance, they are potential or current targets for nutrition interventions, and they are current or potential targets for policy changes (e.g. eliminating soda in schools initiatives), and thus also have great potential to evaluate changes in dietary intake due to policy changes. The DTQ consists of 26 questions. These questions are asked of all individuals, aged 2 and above. Participants ages 12 years and older answer the questions for themselves. The questionnaire is interviewer-administered during the MEC Interview. The information is being collected for participants, ages 2-11 years old, during the Household Interview.

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The results from the pilot study will be used to assess the new instrument's compatibility with the survey protocol and for research purposes, aimed at estimating usual intake of frequently consumed foods.

Pilot Test of Flexible Consumer Behavior Survey (FCBS)

A pilot study was scheduled from June 11 through August 28, 2008 to evaluate adding 10 new questions to the phone follow up element of the FCBS module in the NHANES. The new questions will be integrated into the existing FCBS follow up questionnaire which is currently administered through telephone 3 to 10 days after the physical exams in the Mobile Examination Center. Results from the pilot study will be used to assess and improve these new questions' validity, and determine the feasibility of inclusion in the NHANES. NCHS and Westat staff will periodically observe data collection. Summary data will be discussed with the Economic Research Service, the NHANES FCBS questionnaire sponsor.

Pilot Test of Urine Flow Rate

The pilot for the urine flow rate is scheduled to take place from October 15, 2008 through December 15, 2008. All survey participants, 6 years and older are eligible to participate in the pilot. The objective of the pilot is to estimate the concentration of environmental toxicants in urine. Three measures are needed to calculate the urine flow rate in NHANES: 1) time of urine collection in the mobile examination center (MEC), 2) volume of specimen collected in the MEC and 3) time of the previous urine void prior to specimen collection in the MEC.

Before arriving at the exam center, the participant will make a note of the time he/she last went to the bathroom and urinated. Upon arrival at the exam center the participant will be instructed to collect a urine specimen. In the laboratory the medical technologist will record 1) time of urine collection in the mobile examination center (MEC), 2) volume of specimen collected in the MEC and the coordinator will record the time of the previous urine void prior to specimen collection in the MEC. The urine flow rate will be calculated from these three items.

Evaluation will include: (1) review of the data collected to evaluate the quality and completeness of the data and (2) evaluation of details of the protocol. NCHS and Westat staff will periodically observe data collection. There are no safety exclusions for urine flow rate and survey participants will not receive a report of findings.

Pilot Test of Albumin/Creatinine Ratio Urine Collection

The pilot for the second urine collection to measure the albumin/creatinine ratio is scheduled to take place from September 23, 2008 through November 22, 2008. All survey participants 6 years and older are eligible to participate in the pilot. The objectives of the pilot are to assess persistent microalbuminuria in the U.S. population; and 2) determine if a second urine sample can be collected in the participant's home and shipped directly to an analytical laboratory.

A urine specimen is currently collected in the MEC on all examined persons 6 years and older. Specimens are sent to a testing laboratory for urine creatinine and albumin

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measurements. The laboratory reports the results of the urine analysis to NCHS within 21 days of the MEC examination. For the pilot and 2009-10 protocol if the urine albumin to urine creatinine ratio (ACR) is greater than 10 mg/g, the survey participant will be asked to provide a second urine sample via a home urine collection kit. During the pilot test, all participants will be asked to participate in the second urine specimen collection. A urine collection kit will be given to the survey participant in the MEC. The kit will have instructions on how to collect and mail the urine specimen to the testing laboratory.

Evaluation will include: (1) review of the data collected to evaluate the quality and completeness of the data and (2) evaluation of details of the protocol. There are no safety exclusions for the urine albumin/creatinine ratio and survey participants will receive a report of finding.

Pilot Test of Reactions to Race Questionnaire

A pilot study, of a 10 question reactions to race audio computer-assisted self-interview (ACASI) module, is being planned for August 17, 2008 through October 7, 2008. The purpose of these questions is to collect information on respondents' perceptions of differential treatment, based on race or ethnicity (in the case of Hispanics) and its impact on their health. Survey participants will answer 10 questions (in English or in Spanish) independently using an ACASI interview module.

Pilot Test of Oral HPV

During the Oral Health Component training in November 2008 specimen collection for the Human Papilloma Virus rinse will be pilot tested. The collection consists of a 30 second oral rinse and gargle with Scope brand mouthwash or saline. Participants ages 14-69 will alternate a series of three, five second rinse and five second gargles with 10 ml of Scope or saline. The Scope or saline is then expectorated into a sterile collection cup and transported to the MEC laboratory and refrigerated at 4oC. The HPV pilot collection will continue until mid-December if necessary.

Pilot Test of Food Stamp and WIC administration record linkage

A feasibility/pilot test linking NHANES records to Food Stamp and WIC Program administrative records is planned for one or more NHANES locations from NHANES 2007-2008. If successful this may become part of the protocol for future NHANES. An OMB Change Form document will be generated when a detailed protocol is developed.

Pilot Testing for NHANES 2011-2012

All pilot/feasibility testing must be concurrent to the ongoing data collection within the framework of the survey. DHANES proposes continuing to pilot test the procedures for 2011-2012 as we have done in 2008 for 2009-2010. We plan to start piloting and developing methods in the spring of 2009. NHANES will continue to request permission to conduct pilot and methodological studies through the use of the OMB Change Form mechanism. Attachment 11 contains an example (described below) of special studies/pretests done in preparation for NHANES 2009-2010.

Cognitive testing of the new questions planned for NHANES 2009-2010

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This cognitive testing was designed to evaluate the new questions planned for NHANES 2009-2010. It was conducted with volunteer respondents in February and March of 2008, and is an example of a NHANES special study/pretest. Four sets of questions were included in this project:

- a) Inflammatory arthritis questionnaire (Attachment 11, part A);
- b) New additions to the Flexible Consumer Behavior Survey (FCBS) phone follow-up module (Attachment11, part B);
- c) Dietary screener module (Attachment, part C); and
- d) Reactions to race/ethnicity questionnaire (Attachment, part D)

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
LRC2@cdc.gov

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
CLJ1@cdc.gov

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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Centers for Disease Control and Prevention

Phone: 301-458-4292

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- Attachment 1 – Applicable Laws or Regulations (Excerpts)
- Attachment 2a – Federal Register Notice
- Attachment 2b- Responses to Federal Register Notice
- Attachment 3 – Agencies consulted and Interagency Agreements Expected for 2009-10
- Attachment 4 – Letters and Scripts
- Attachment 5 – Informed Consent Brochures
- Attachment 6 – Most recent IRB Review and Approval September 30, 2005
- Attachment 7 – Sampling Information
- Attachment 8 – Laboratory Component
- Attachment 9 – MEC Data Collection Forms and NHANES Questionnaires

- Attachment 10 – Report of Findings
- Attachment 11 – Example of Special Study/Pretest