DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control and Prevention
National Center for Health Statistics
3311 Toledo Road, Room 4330
Hyattsville, Maryland 20782

Date: June 28, 2005

From: Clifford Johnson, M.S.P.H.
Director
National Health and Nutrition Examination Survey
National Center for Health Statistics/CDC

Subject: Proposal guidelines for new content on the 2009-2010 National Health and Nutrition Examination Survey (NHANES)

To: Potential and Current NHANES Collaborators

NCHS will consider adding new or revised questionnaire material, laboratory assessments, and examination components to the survey. Please note that the ability to add examination components or new questionnaire items is limited by logistical considerations (time) and dependent on other content cycling out of the survey. Proposals of merit received for consideration in 2007-8 but not added to the protocol will be considered with the highest priority for 2009-10. Proposals for inclusion in 2009 may be deferred for consideration until 2011 if that is of interest to the party proposing.

The proposal submission process is a 2-stage process. Initially, all proposers should submit a letter of intent describing the proposed NHANES project. The letter of intent should be brief (two pages maximum) and include brief descriptions of the public health significance of the proposal, technical requirements to perform the proposed component, and issues related to the safety and privacy of survey participants. NCHS will review the letters of intent and provide comments to proposers. If the proposal is selected for further consideration a full research proposal will be requested.

The final date for letters of intent to be received is **September 15, 2006**. NCHS will notify proposers by **December 1, 2006** as to whether a proposal will be given further review. The proposers will have until **February 28, 2007** to submit the final research proposal. **Proposers are strongly encouraged to make their proposals for 2009-10 well in advance of these deadlines.** Proposal Guidelines are provided in Attachment 1.

Prior to submitting your research proposal, we request that you review the NHANES questionnaires, examination components, and laboratory tests that are on the NHANES website: http://www.cdc.gov/nchs/about/major/nhanes/questexam.htm

NCHS requests that all proposers include funding source information in their proposals. Proposers must guarantee a minimum of two years of financial support for new survey content.

Because new content requires testing and piloting prior to full implementation in the survey, the sponsoring group(s) should be prepared to cover these costs starting in FY 2007.

The NHANES Planning Branch can assist you in preparing your proposal. We will acknowledge receipt of your letter of intent and research proposal via e-mail. To clarify requirements for the research proposals or to schedule a meeting, please contact Vicki Burt, Chief, Planning Branch at 301-458-4127 or a member of the Planning Branch staff.

Joint proposals both within CDC, with other Federal agencies, and with groups outside the government are encouraged.

Please send all NHANES 2009-2010 letters of intent and research proposals to:

Ms. Darlene Cherry
National Center for Health Statistics
Division of Health Examination Statistics
3311 Toledo Road, Room 4330
Hyattsville, MD 20782
E mail: DCherry1@cdc.gov

Attachment 1

PROPOSAL GUIDELINES
NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES) 2009-2010

NHANES Overview

The National Center for Health Statistics (NCHS), Division of Health Examination Statistics (DHES), part of the Centers for Disease Control and Prevention (CDC), has conducted a unique series of health and nutrition surveys since the early 1960's. Extensive interview and health examination data are obtained. NHANES were conducted on a periodic basis from 1971 to 1994. NHANES are now conducted on a continuous basis. Each year, approximately 6000 individuals, of all ages, are interviewed in their homes; of these, approximately 5,000 complete the examination component. The health examinations are conducted in mobile examination centers (MECs). NHANES provides an ideal setting for the collection of high quality data in a standardized environment. The target population for NHANES survey participant is the civilian, noninstitutionalized U.S. population. In 2009-10, NHANES will over sample low-income persons, persons 60 years of age and older, African Americans and Hispanic Americans.

The major objectives of NHANES are:

1. To estimate the number and percent of persons in the U.S. population and designated subgroups with selected diseases and risk factors,
2. To monitor trends in the prevalence, awareness, treatment and control of selected diseases,
3. To monitor trends in risk behaviors and environmental exposures,
4. To analyze risk factors for selected diseases,
5. To study the relationship between diet, nutrition and health,
6. To explore emerging public health issues and new technologies;
7. To establish a national probability sample of genetic material for future genetic research;
8. To establish and maintain a national probability sample of baseline information on health and nutritional status.

NHANES 2009-2010 Research Proposal Guidelines

Section 1: Title Page

X Proposal Title
X Abstract
X Table of contents
X Author(s): Please designate a primary contact person
X Institutional affiliation, mailing address, and phone and fax numbers, e-mail address of all authors. (Note: CDC Proposers: Please include CDC Ethics Verification Numbers of CDC investigators.)

Section 2: **Project Description**

1. Introduction: Brief history and description of topic area, proposed target population and aims of the proposed research.

2. Public Health Significance

   Proposals need to address public health significance in specific terms. The following are examples of relevant topic areas with public health significance. Please address the following, as appropriate:

   a. Surveillance: Is this proposal designed to produce national population health and nutrition parameters? Is the prevalence of this condition known, and/or is the prevalence of this condition expected to change in the future?

   b. Prevention: What significance would this proposal potentially have in the prevention of diseases and their related morbidity and mortality?

   c. Treatment: Will the resulting data be used to assess the effectiveness of treatment or the extent of untreated disease (i.e., awareness, treatment and control of hypertension)?

   d. Health promotion/disease prevention objectives: Would this proposal provide baseline data or be used to assess progress for Healthy People 2010 objectives? If yes, list the objectives and the relevance of the proposed project.

   e. Health policy: How will this proposal address a public health concern that will help decision makers design effective public health programs?

   f. Program evaluation: Will the findings be used to evaluate Federal programs? For example, would this proposal help to assess knowledge, attitudes, practices and progress of health and nutrition education campaigns, such as: the National Cholesterol Education Program, National High Blood Pressure Education Program, 5-A-Day

Initiative, the USDA Supplemental Feeding Program for Women, Infants, and Children (WIC), the Food Stamp Program, the Obesity Education Initiative, Dietary Guidelines for Americans, food fortification policy initiatives, or other programs?

g. Health disparities: Will the data be used to assess the health and nutrition status of racial and ethnic minorities and under-served populations?

Section 3: Data Collection

Describe the design and methodology of the proposed component including any or all of the following: survey questions, laboratory assays, and examination protocols. If the proposed methods have been used in other major health studies, please provide the names and telephone numbers of the principal investigators; NCHS staff may wish to contact them to discuss the research methods. Please address the following points in this section:

a. Validity and reliability of the methods: New survey content receives careful scrutiny from the Office of Management and Budget (OMB) and others before the material is added to NHANES. Include copies of key journal articles that document the validity and reliability of the proposed methods in an appendix section to this proposal. Discuss potential difficulties and limitations of the proposed methods, their appropriateness for use in the proposed population target groups, cross-cultural validation, translation validation research, and readability testing. For new or revised survey questionnaire items, identify other surveys or studies that have used the questions. Summarize pertinent findings from previous studies and provide data from cognitive laboratory research testing; address any issues related to potential differences in the validity and reliability of findings across study subgroups.

b. Biologic Specimen Collection Methods: Describe collection procedures for obtaining biologic specimens. Provide justification if a non-standard specimen collection method is proposed. The ease of specimen collection and amounts required for tests, particularly in young children are evaluated carefully. Please describe ease of collection, required specimen amounts (weights or volumes), and specimen storage requirements.

c. Respondent burden. Estimate the time required for a survey participant to respond to the questionnaire items. In the case of examination components, assurance is needed that the total exam will be no longer than ten minutes. For questions, be sure to include the estimated burden, whether interview aids such as hand cards, supporting data bases or look-up files are needed, and other issues that impact on data collection.

d. Proxy Reporting: For questions that target children, specify the age range requiring a proxy/parent respondent.

e. Respondent privacy: If the proposed questions or examination contents are sensitive in nature, please propose methods to maintain privacy, minimize

embarrassment and reduce item nonresponse. Address privacy considerations if a child answers for him/herself

f. Reporting results to respondents: If the results of the laboratory assay or examinations have clinical significance for survey participants, describe the ethical issues regarding the reporting the results to the Survey participant. Give us an example of how you would report this finding to a survey participant. Cite the methods used in other health studies as appropriate. If the results are not to be reported, the rationale for this decision must be justifiable.

g. References and citations: Document that the proposed methods are well established and capable of being administered in a standardized manner.

h. Target Group: State the gender and age ranges and anticipated annual sample sizes for the proposed component.

i. Questionnaire Material Placement: Where will the new questionnaire items be administered? Specify whether the questions will be part of the household interview or the health examination component. If you are unsure of the content of the current questionnaires, please check with NCHS staff to obtain information about the NHANES questionnaires.

j. Data analysis, grading, and/or interpretation: How will the data or specimens be processed? Specifically, who will perform laboratory analyses, file reading, data scoring, interpretation, and preparation of the final data? Be sure to specify the laboratories, research groups, or other parties who will be involved in the preparation of the data for this component. If multiple groups are involved in the data preparation process, please be sure to identify the groups, the steps required to process the data or analyze specimens, the responsibilities of each party, and a plan for producing final survey data files.

k. Equipment: Provide a brief description of the required equipment, if applicable. What criteria were used to select the equipment for use in NHANES? Has the equipment been used in other large-scale research studies? Describe the equipment calibration procedures, hardware requirements for operation, data storage, and data transmittal, survey staff training requirements, and essential technical requirements for all equipment used in this component. This information will be used to assess the amount of effort and testing required to integrate the proposed component into NHANES.

l. Software Requirements: Brief description of the software requirements for specialized instruments. Who has the copyright for the software? Are maintenance agreements and licenses required? What is the cost of the software? Hardware platform requirements should also be described briefly.

m. Laboratory and Clinical Test Characteristics: What is the specificity and sensitivity of the proposed test?

n. Staffing Requirements: Describe the staffing requirements to conduct this component in the field and produce data files for analysis. Please include the required qualifications, certifications, (if applicable) required training, and other skills for survey staff involved in conducting this component. Describe recertification and quality control monitoring requirements to ensure that data collection, laboratory performance, and equipment performance is maintained at an acceptable level.

o. Time requirements: How much time is required to collect the information, data, and/or specimens for this component? Examination component time is computed from the time the respondents enter the examination room until they leave. Interview time is the total amount of time required to administer questions and record responses. Describe the sequence of steps involved in data collection. For clinical and laboratory tests estimate the time required to explain the component, prepare the respondent for the test, conduct the test, and complete the post-examination procedures, clean-up, and so forth. If a significant percentage of tests are expected to be repeated due to participant or technician error, please describe this in the proposal.

p. Quality control requirements: Please describe requirements for technician monitoring in the field, biomedical and laboratory equipment calibration checks, and data quality monitoring during the survey. Identify problems that have occurred in similar field studies and how such problems can be avoided or minimized in NHANES.

Section 4: Supplementary documents

1. Laboratory Assays

NCHS is the primary contractor on all contracts with laboratories that perform analyses with NHANES specimens. Survey collaborators are not permitted to contract directly with outside laboratories. NCHS is the only party that has direct access to laboratory findings and quality control data from the NHANES contract laboratories.

a. Describe the processing required in the field and any time constraints for handling, also the quantity of blood, urine or other laboratory-based specimen required. Laboratory assays should use the least amount of a specimen. Attach specifics of laboratory method in an appendix.

b. Describe the sensitivity and specificity of the assay and whether it is FDA approved.

c. Discuss whether the assay is considered 'state-of-the-art' or if it is still developing.

2. Equipment- Please describe the following items if they are applicable to the proposal:

   a. Equipment maintenance provisions

   b. Safety precautions. Identify subject exclusion criteria, if applicable.

   c. Provide the dimensions of the equipment including weight

   d. Describe the equipment calibration procedures

   e. Describe daily start-up and shutdown procedures

   f. Portability- Can the equipment be moved several times per year without adverse in mobile trailers without adverse consequences? Has this equipment be used in similar studies? If so, describe the experiences and any problems encountered using the equipment.

   g. Describe environmental considerations if applicable. Factors such as temperature, humidity, vibrations, sound, ventilation, voltage, hardware/software, and placement within the mobile exam center should be addressed.

   h. Equipment manufacturer guarantees, i.e. the availability of maintenance, replacement parts, and possibly replacement equipment to survey sites located throughout the country? Describe measures that will be taken to ensure that equipment problems will not interfere with survey data collection activities.

   i. Confirm that the equipment specified for use in the survey will be available for at least two years of survey data collection.

   j. Provide technical descriptions, manuals, and cost information for all required equipment used with this component.

Section 5: Project Budget

NCHS requests that all proposers include funding source information in their proposals. In most instances, proposers must guarantee a minimum of two years of financial support for new survey content. Additionally, new survey content often requires pretesting or a small pilot study prior to full-scale implementation in the survey. The sponsoring group(s) should be prepared to cover pre- or pilot test costs starting in FY 2007.

NCHS will prepare a preliminary cost for the proposed content based on the information provided in the letter of intent and proposal, and information exchanged at the time the proposal is being considered for likely inclusion in the survey. Any information you can provide regarding equipment costs, laboratory costs, and other component-related costs will assist us in this endeavor.

If your proposal is selected for the second stage of the review process and is considered for inclusion on the 2009-2010 NHANES, the preliminary cost estimates will also include an estimate to pilot test the content in NHANES 2007 or 2008. The need for pilot testing will depend on the nature of the proposed content.

Section 6. Instructions for Formatting and Submitting Research Proposals

In general, proposals should be both explicit and brief. Be sure to specify the objectives of the component, the design of the research protocol, and the target population. Please provide published reports and articles, including validation studies, expert panel reviews, and study reports from studies that have used the proposed methodology. Details as to the instrument, relevant literature and research, budget, and data collection methods should be included in appendices.

The project description (Section 2) should not exceed 10 pages in length. While there is no page limit for the supplementary documents (Section 4), only information that is relevant to the proposal should be included. Each section of the proposal should be paginated separately, with the page number in the bottom center of each page.

Three printed copies of the proposal should be provided to NCHS. In addition, please submit an electronic version of the proposal, preferably in Word; printed copies of reference articles and technical materials are acceptable. E-mail the electronic version of proposal to KOraegbu@cdc.gov.

How will NHANES research proposals be evaluated?

The proposal evaluation factors are: 1) public health significance , 2) scientific merit , 3) relevance to NHANES, and 4) methodological and technical feasibility. Specific issues to discuss in the proposal to address the evaluation factors are described below.

1) Public Health Significance: Relate the proposal to a new or unstudied public health issue, or ongoing monitoring of a significant public health problem.

- Describe what is known about the magnitude of the problem or issue to be addressed in the total U.S. population and population subgroups.

- If a health condition or disease is rare in the U.S. population (i.e., prevalence < 5 percent), the proposal should state the reasons to assess such a component or condition in NHANES. Provide background calculations to

show that the NHANES sample sizes will be sufficient to compute prevalence estimates.

- Cite national policy and program recommendations or long-term health objectives that require this information when appropriate.

2) Scientific Merit

- Are the proposed methods for this component comparable with previous research and accepted standards for studying the issue? If a different method or approach will be used to study this question, please provide justification for the alternative approach.

- What will be gained from collecting the proposed data?

- Interpretive criteria for the proposed component: What cut-points, scores, and so forth are used to define Anormal@ and Aabnormal@ findings? What are the bases for these criteria?

- Provide summarized findings and references to document the scientific validity and reliability of the proposed survey questions and/or examination and laboratory methods to estimate the extent of a health problem or condition in the U.S. population.

- The proposal is expected to pass full NHANES Institutional Review Board (IRB) review prior to implementation. The review will address respondent burden, safety, informed consent, confidentiality, and report of findings. Please address potential IRB review concerns based upon past research experiences.

- Are the proposed methods and instruments appropriate for use in a national population survey?

- Are expert groups supportive of efforts to assess this problem in NHANES? If so, please cite their recommendations.

- If this component was included in previous NHANES, explain why it should be repeated in NHANES 2009-2010.

3) Relevance to NHANES

- If this component was included in previous NHANES, explain why it should be repeated in NHANES 2009-2010.