- AR–4—HIV/AIDS Confidentiality Provisions
- AR–5—HIV Program Review Panel Requirements
- AR–6—Patient Care
- AR–8—Public Health System Reporting Requirements
- AR–10—Smoke-Free Workplace Requirements
- AR–11—Healthy People 2010
- AR–12—Lobbying Restrictions
- AR–14—Accounting System Requirements
- AR–15—Proof of Non-Profit Status
- AR–21—Small, Minority, and Women-Owned Business
- AR–22—Research Integrity
- AR–23—States and Faith-Based Organizations
- AR–24—Health Insurance Portability and Accountability Act Requirements
- AR–25—Release and Sharing of Data

Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.*

VI.3. Reporting

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, (use form PHS 2590, OMB Number 0925–0001, rev. 5/2001 as posted on the CDC website) no less than 90 days before the end of the first 12 month budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Budget.

e. Additional Requested Information.

f. Measures of Effectiveness.

2. Financial status report no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section—PA #04119, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, telephone: 770–488–2700.

For scientific/research issues, contact: Sheryl Lyss, MD, Extramural Project Officer, CDC, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, MS E–46, Atlanta, Georgia 30333, telephone: 404–639–2093, e-mail: *SLyss@cdc.gov.*

For questions about peer review, contact: Noreen Qualls, Dr.P.H., Scientific Review Administrator, CDC, National Center for HIV, STD, and TB Prevention, Office of the Associate Director for Science, 1600 Clifton Road, NE., Mailstop E–07, Atlanta, GA 30333, telephone number: 404–639–8006, fax: 404–639–8600, e-mail address: *nqualls@cdc.gov.*

For financial, grants management, or budget assistance, contact: Brenda D. Hayes, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, telephone: 770–488–2741, e-mail: *bkh4@cdc.gov.*

For financial, grants management, or budget assistance in the territories, contact: Vincent Falzone, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, telephone: 770–488–2763, e-mail: *vcf6@cdc.gov.*

Dated: May 18, 2004.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04–11643 Filed 5–21–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Participatory Research on Community Interventions to Increase the Utilization of Effective Cancer Preventive and Treatment Services, Program Announcement Number 04087

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Participatory Research on Community Interventions to Increase the Utilization of Effective Cancer Preventive and Treatment Services, Program Announcement Number 04087.

Times and Dates: 8:30 a.m.–9 a.m., June 17, 2004 (Open); 9 a.m.–5 p.m., June 17, 2004 (Closed).

Place: Sheraton Midtown Atlanta Hotel at Colony Square, 188 14th Street at Peachtree, Atlanta, GA 30361, Telephone 404.892.6000.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Participatory Research on Community Interventions to Increase the Utilization of Effective Cancer Preventive and Treatment Services, Program Announcement Number 04087.

Contact Person for More Information: Elizabeth L. Skillen, PhD, Scientific Review Administrator, Public Health Practice Program Office, Centers for Disease Control, 4770 Buford Highway, NE., MS–K38, Atlanta, GA 30341, Telephone 770.488.2592.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: May 18, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–11642 Filed 5–21–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Health and Nutrition Examination Survey (NHANES) Stored Biologic Specimens: Guidelines for Proposals To Use Samples and Proposed Cost Schedule

ACTION: Notice and request for comments.

SUMMARY: The National Health and Nutrition Examination Survey (NHANES) is a program of periodic surveys conducted by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC). Examination surveys, conducted since 1960 by NCHS have provided national estimates of health and nutritional status of the United States civilian non-institutionalized population. To add to the large amount of information collected for the purpose of describing the health of the population in the most recent survey, serum and urine were collected and stored for future research projects.

Specimens are currently available from NHANES III (conducted from 1988-1994) and from NHANES 1999–2002. Participants in the survey that began in 1999 signed a separate consent document agreeing to this storage, and allowing their biologic specimens to be used for approved research projects.

Specimens are stored in two Specimen Banks. Surplus samples that were initially used for laboratory assays included in the surveys, have since been stored at −70 °C and have been through at least two freeze-thaw cycles. They are stored at McKesson BioServices Repository in Rockville, MD. In addition, on average, six vials of sera were also stored in vapor-phase liquid nitrogen at the CDC CASPIR Repository in Lawrenceville, GA. These specimens have not undergone a freeze-thaw cycle. The CASPIR Repository is considered a long-term repository for the NHANES specimens. NCHS is making both of these collections available for research proposals. The research proposals that can use the surplused specimens will receive higher priority. Proposals that request the specimens in CASPIR need to justify the use of the unthawed specimens.

The purpose of this notice is to request comments on this program and the proposed cost schedule. After consideration of comments submitted, CDC will finalize and publish the cost schedule and accept proposals for use of the NHANES stored biologic samples. Please go to *http://www.cdc.gov/nchs/about/major/nhanes/serum1b.htm* for final proposal guidelines.

All interested researchers are encouraged to submit proposals. No funding is provided as part of this solicitation. Samples will not be provided to those projects requiring funding until the project has received funds. Approved projects that do not obtain funding will be canceled. A more complete description of this program follows.

DATES:

- Comment Receipt Date: June 23, 2004.
- Invitation To Submit Proposals: July 23, 2004 or can be received at any time.
- Scientific Review Date: Within two months of proposal submission.
- Institutional Review Date: Within one month of final proposal acceptance.
- Anticipated distribution of samples: one month after IRB approval.

To Send Comments and To Request Information: Dr. Geraldine McQuillan, Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 4204, Hyattsville, MD 20782, telephone: 301–458–4371, fax: 301–458–4028, e-mail *gmm2@cdc.gov*. Internet: *http://www.cdc.gov/nchs/about/major/nhanes/serum1b.htm*.

SUPPLEMENTARY INFORMATION: The goals of NHANES are: to estimate the number and percent of persons in the U.S. population and designated subgroups with selected diseases and risk factors; to monitor trends in the prevalence, awareness, treatment and control of selected diseases; to monitor trends in risk behaviors and environmental exposures; to analyze risk factors for selected diseases; to study the relationship between diet, nutrition and health; to explore emerging public health issues and new technologies; and, to establish and maintain a national probability sample of baseline information on health and nutrition status.

Specimens are available from NHANES III, which was conducted from 1988–1994 and the current cycle of NHANES where data has been released (1999–2002). In the future, specimens will be available for a two-year cycle of NHANES after the public release of the collected data. The current National Health and Nutrition Examination Survey (NHANES) began in April 1999 and is a continuous yearly study. Data are released on a two-year cycle, and proposed research projects and samples requested must come from this two-year design (*i.e.* request must be for 1999–2000 samples or 2001–2002, etc.). Samples from a single year of the survey will not be provided for research projects, but multiple two-year cycles (*i.e.* four years) may be requested but should be justified. For details of the sampling design see the Analytic Guidelines at: *http://www.cdc.gov/nchs/about/major/nhanes/NHANES99_00.htm*.

The third National Health and Nutrition Examination Survey (NHANES III) began in the fall of 1988, and ended in the fall of 1994. The survey can be analyzed in two phases. Phase 1 was conducted from October 1988 to October 1991. Phase 2 began October 1991 and ended October 1994. Approximately 30,000 individuals were examined during the six years of the survey with 15,000 in each three-year sample. See: *http://www.cdc.gov/nchs/about/major/nhanes/datalink.htm#NHANESIII* for more information on NHANES III.

Survey participants in the current NHANES which began in 1999, who signed the consent document for future research, were informed that they would not receive the results from these studies. Therefore, only research projects that propose laboratory results that do not have clinical relevance to an individual will be accepted by NCHS. Clinical significance of a laboratory test will be judged by the NHANES Medical Officer, but the researcher should address this in the research proposal. See *http://www.cdc.gov/nchs/data/nhanes/00futstu.pdf* for a copy of the consent document. Though storage of blood specimens for future research was mentioned in the NHANES III consent document, a separate consent for use of these specimens was not obtained. The NHANES Ethics Review Board (ERB) has accepted the language in the NHANES III consent document to cover the use of the specimens, but only research projects that include results that are judged not to have clinical significance for participants will be accepted.

All proposals for use of NHANES samples will be evaluated by a technical panel for scientific merit and by the NHANES ERB for any potential human subjects concerns. The NHANES ERB will review the proposal even if the investigator has received approval by their institutional review panel.

The Technical Panel will evaluate the public health significance and scientific merit of the proposed research. Scientific merit will be judged as to the scientific, technical or medical significance of the research, the appropriateness and adequacy of the experimental approach, and the methodology proposed to reach the research goals. See ''Criteria for Technical Evaluation of Proposals'' below. The proposal should outline how the results from the laboratory analysis will be used. Because NHANES is a complex, multistage probability sample of the national population, the appropriateness of the NHANES sample to address the goals of the proposal will be an important aspect of scientific merit. The Technical Panel will assure that the proposed project does not go beyond either the general purpose for collecting the samples in the survey, or of the specific stated goals of the proposal.

Investigators are encouraged to review the NHANES data, survey documents, manuals and questionnaires at: *http://www.cdc.gov/nchs/about/major/nhanes/nhanes99–02.htm* or for NHANES III: *http://www.cdc.gov/nchs/about/major/nhanes/nh3data.htm*.

NHANES is a representative sample of the U.S. population. The survey oversamples the two largest race/ethnic minority groups, non-Hispanic blacks and Mexican Americans along with other subgroups of the population.

Sampling weights are therefore used to make national estimates of frequencies. The use of weights, sampling frame and methods of assessment of variables included in the data are likely to affect the proposed research. The Technical Panel will review the analysis plan and evaluate whether the proposal is an appropriate use of the NHANES population. Since data from NHANES 99+ is released in two-year cycles, proposals will only be accepted for use of specimens from the two years of a release cycle. Multiple two-year cycles may be requested but the need for the additional sample size should be justified. Proposals for NHANES III can request specimens from one or both phases of the survey.

Procedures for Proposals

All investigators (including CDC investigators) must submit a proposal for use of NHANES specimens.

Proposals are limited to a maximum of ten single-spaced typed pages, excluding figures and tables, using ten cpi type density. The cover of the proposal should include the name, address, and phone number and e-mail address of the principal investigator (PI) and the name of the institution where the laboratory analysis will be done. All proposals should be e-mailed to *gmm2@cdc.gov*.

The Criteria for Technical Evaluation of Proposals section at the end of this announcement and the following information should be used to develop the proposal content.

Research proposals that can use the NHANES III specimens, which has a large number of available samples but come from an earlier time period, will receive priority.

1. Specific Aims—List the broad objectives; describe concisely and realistically what the research is intended to accomplish, and state the specific hypotheses to be tested. NHANES is designed to provide prevalence estimates of diseases or conditions that are expected to affect between 5–10 percent of the population. Research proposals that expect much lower prevalence estimates need to provide more detail on why specimens from NHANES are needed for the project and provide details on how these data will be analyzed.

2. Background and Public Health Significance—Briefly describe in 1–2 pages the background of the proposal, identifying gaps in knowledge that the project is intended to fill. State concisely the importance of the research in terms of the broad, long-term objectives and public health relevance including a discussion of how the results will affect public health policy or further scientific knowledge. The proposal should justify the need for specimens that are representative of the U.S. population. Studies that do not need a national sample or request a subset of samples such that estimates cannot be weighted to make national estimates will not be accepted.

3. Clinical Significance or results—Since the consent document for specimen storage and continuing studies states that individual results will not be provided, the clinical significance of the proposed laboratory test should be addressed. The proposal should include a discussion of the potential clinical significance of the results and whether there is definitive evidence that results of the test would provide grounds for medical intervention. Any test with results that should be reported to a participant should be considered for inclusion in the concurrent survey, and is not appropriate for testing on the stored samples.

4. Research Design and Methods—Describe the research design and the procedures to be used. A detailed description of laboratory methods must be included with references. Laboratory quality control should be described. Include a justification for determination of sample size or a power calculation. If the researcher is requesting a sub-sample of specimens, a detailed description and justification, must be given. The researcher must describe how this sub-sample will be re-weighted to provide national estimates. The program will evaluate the study design and analysis plan in the proposal to determine whether the project is consistent with the design of the NHANES survey. Sub-samples are less useful to the research community when the data are released in the public domain, so such requests will receive a lower priority for the specimens. Restricting a research proposal to demographic categories that are design variables for the survey is encouraged if laboratory testing must be restricted.

5. Qualification of Investigators—A brief description of the Principal Investigator's expertise in the proposed area should be provided, including publications in this area within the last three years. A representative sample of earlier publications may be listed as long as this section does not exceed two pages.

6. Funding—The source and status of the funding to perform the requested laboratory analysis should be included. Investigators will be responsible for the cost of processing and shipping the samples. At this time the cost per specimen is $2.00. The basis for the cost structure is in the last section of this document. Reimbursement for the samples will be collected before the samples are released.

7. Timeline for laboratory tests—NHANES ERB approval of the individual research projects must be renewed every year. Investigators must have substantial progress (defined by the start of laboratory testing) in the first year, and all testing should be completed in the second year. The investigator should address his/her ability to comply with this timeline or request and justify additional time for the project. Return of the specimens will be requested if progress is not made in the project at the end of the second year. Refund of payment for the specimens will not be returned in this situation.

Requirements for the Inclusion of Women and Racial and Ethnic Minorities in Research

The following policy must be followed in the submitted proposals:

It is the policy of the CDC and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in the CDC/ATSDR—supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in the OMB Directive No, 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander. Applicants shall ensure that women and racial ethnic minority populations are appropriately represented in applications for research involving human subjects. When clear and compelling rationale exists that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, pages 47947–47951, and dated Friday, September 15, 1995.

Submission of Proposals

Investigators are invited to submit proposals in MS Word format by e-mail to: Dr. Geraldine McQuillan, Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 4204 Hyattsville, MD 20782, telephone: 301–458–4371, fax: 301–458–4028, e-mail *gmm2@cdc.gov*.

Criteria for Technical Evaluation of Proposals

The following criteria will be used for technical evaluation of proposals:

1. Background and Public Health Significance: The public health significance, scientific merit and practical utility of the assay. The proposer should convey how the results will be used and the relationship of the results to the data already collected in NHANES. The proposer should include an analysis plan. The analyses ought to be consistent with the NHANES mission and the health status variables.

2. Research Design and Methods: The sampling scheme or age/race-ethnic/gender categories for the testing must be described and addressed with regards to its relationship to the NHANES design. Power calculations for a sub-sample must be included (*see* Procedures for Proposals for evaluation of proposals that suggest use of sub-samples). A list of variables that will be used in the initial data analyses should be included to demonstrate familiarity by the proposer with the dataset.

A detailed description of the laboratory methods should be included. The characteristics of the laboratory assay, such as reliability, validity, and ''state-of-the-art'', must be included with appropriate references. The potential difficulties and limitations of the proposed procedures should be discussed. The volume of specimen and the number of samples required should be specified. Adequate methods for handling and storage of samples must also be addressed. The laboratory must demonstrate expertise in the proposed laboratory test and the capability for handling the workload requested in the proposal.

3. Clinical Significance or results: Since the current consent document for specimen storage and continuing studies states that individual results will not be provided, the clinical significance of the proposed laboratory test should be addressed. The proposal should include a discussion of the potential clinical significance of the results and whether there is definitive evidence that results of the test would provide grounds for medical intervention. Any test with results that should be reported to a participant should be considered for inclusion in the concurrent survey, and are not appropriate for testing on the stored samples.

4. Discussion regarding the race/ethnicity variables: If all race/ethnic groups are not requested, the proposal gives a clear and compelling rationale for not including them.

5. Qualifications: A brief description of the requestor's expertise in the proposed area must be provided including publications in this area within the last three years. A representative sample of earlier publications may be listed as long as this section does not exceed two pages.

6. Period of performance—The project period should be specified. Substantial progress must be made in the first year, and the project should be completed in two years. If additional time is needed for the research project a detailed justification with a timeline should be included. At the end of the project period, any unused samples must be returned to the NHANES Specimen Bank or discarded. The NCHS Project Officer must be consulted about the disposition of the samples.

Approved Proposals

Approved projects will be provided specimens on receipt of a signed Materials Transfer Agreement (MTA) and a check (written to ''The Centers for Disease Control and Prevention'') for the cost of the specimens. All laboratory results obtained from the samples will be sent back to NCHS to be linked to the sequence number that is the linking identifier on the public use files. Within six months of the return of the data to NCHS, these data may be released to the public.

Agency Agreement

A formal signed agreement in the form of a Materials Transfer Agreement (MTA) with individuals who have projects approved will be completed before the release of the samples. This agreement will contain the conditions for use of the samples as stated in this document and as agreed upon by the investigators and CDC.

Progress Reports

Brief progress report will be submitted annually. This will be the basis for the NHANES ERB continuation reports that are also required annually.

Disposition of Results and Samples

No samples provided can be used for any purpose other than those specifically requested in the proposal and approved by the Technical Panel and the NHANES ERB. No sample can be shared with others, including other investigators, unless specified in the proposal and so approved. Any unused samples must be returned to the Bank or disposed of upon completion of the approved project.

These results, once returned to NCHS, will be part of the public domain. The data will not be released until approximately six months after reporting the results to NCHS, to allow the investigator time to publish results, unless otherwise required by Federal law.

Proposed Cost Schedule for Providing NHANES III DNA Specimen Bank

A nominal processing fee of $2.00 is proposed for each sample received from the NHANES Specimen Bank. The costs include both the collection, storage and processing of the specimens along with the review of proposals and the preparation of the data files. These costs were based on an assumption that NCHS will receive and process four proposals in a year, each requesting 5000 samples as shown in the table below.

The materials listed are for the recurring laboratory costs to dispense and prepare the samples during collection and for shipping; the computer software needed for the preparation of the data files and for the release of the data along with documentation on the NHANES Web page. Labor costs are based on a proposal administrator and computer programmers at NCHS to prepare the data files. The storage fee is the cost of storage at the NHANES repository.

Total costs	Cost per vial
Labor	$0.30
Storage	0.28
Pulling specimens	0.68
Shipping	0.20
Subtotal	1.46
NCHS overhead (15%)	0.22
Subtotal	1.68
CDC/FMO overhead (20%)	0.34
Total	2.00

Comments are solicited on the proposed cost schedule. Comments are due by: June 23, 2004.

Send Comments and Requests for Information to: Dr. Geraldine McQuillan, Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 4204 Hyattsville, MD 20782, phone: 301–458–4371; fax: 301–458–4028, e-mail *gmm2@cdc.gov*.

Dated: May 12, 2004.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention.

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