DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Health and Nutrition Examination Survey (NHANES) DNA Samples: Guidelines for Proposals To Use Samples and Cost Schedule

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice.

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 the health and nutritional status of the U.S. civilian non-institutionalized population. To add to the extensive amount of information collected for the purpose of describing the health of the population, DNA specimens were collected during three NHANES surveys. DNA is available in the form of crude lysates of cell lines derived from 7,159 participants enrolled in Phase II of NHANES III (1991–1994). In addition, DNA purified from whole blood is also available from 7,839 participants enrolled in the NHANES 1999–2002 and 4,615 participants enrolled in NHANES 2007–2008. All specimens (NHANES III, NHANES 1999–2002 and NHANES 2007–2008) were sent to the Division of Laboratory Sciences (DLS) at the National Center for Environmental Health (NCEH) for processing. DNA samples from these specimens are being made available to the research community for genetic analyses.

No funding is provided as part of this solicitation. NCHS will review proposals twice a year, in January and July. Proposals will be reviewed by a technical panel and by an internal Secondary Review Committee of senior CDC scientists. The Secondary Review Committee will perform a programmatic review based on the results of the technical review panel and consider the scientific and technical results from the first level of review, important programmatic considerations such as program priorities, program relevance, and other criteria germane to this announcement and to CDC. Projects approved by both reviews will be submitted to the NCHS Ethics Review Board for final approval.

Approved projects that do not obtain funding on their own will be canceled. A more complete description of this program follows.

DATES:

- *Submission of Proposals:* On January 1 and July 1 of each year.
- *Scientific Review:* 30 days after proposal submission date.
- *Secondary Review:* Approximately 30 days after Scientific review is complete.
- *Ethics Review Board:* Approximately 30 days after Secondary review is complete.
- *Notification of approval:* Approximately 30 days after ERB approval.
- *Anticipated distribution of samples:* Approximately 60 days after all approvals are obtained.

Note: Timeframe may vary depending on the nature of the proposal and the results of each level of review. Unforeseen circumstances could result in a change to this schedule.

ADDRESSES: To send comments and for information, contact: Geraldine McQuillan, PhD, 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: *NHANESgenetics@cdc.gov.*

Authority: Sections 301, 306 and 308 of the Public Health Service Act (42 U.S.C. 241, 2421 and 242m).

SUPPLEMENTARY INFORMATION: The goals of NHANES are (1) To estimate the number and percentage of people in the U.S. population and designated subgroups with selected diseases and risk factors for those diseases; (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 relation among diet, nutrition and health; (6) to explore emerging public health issues and new technologies; (7) to establish and maintain a national probability sample of baseline information on health and nutritional status.

The availability of the NHANES III DNA samples has been previously announced (Thursday, August 8, 2002 [67 FR 51585], Friday, January 13, 2006 [71 FR 22248]), Thursday, October 18, 2007 [72 FR 59094] and Thursday, September 3, 2009 [(74 FR 45644)]. NHANES III DNA samples are in the form of crude cell lysates available from the cell lines derived from samples obtained from Phase II (1991–1994) participants. DNA concentrations are unknown and vary between samples (*see* NHANES III DNA Samples section for a description).

Beginning in 1999, NHANES became a continuous, annual survey rather than a periodic survey. For a variety of reasons, including disclosure and reliability issues, the survey data are released on public use data files every two years. In addition to the analysis of data from any two year cycle, it is possible to combine two cycles to increase sample size and analytic options. Blood samples for DNA purification were collected from participants age 20 or more years in survey years 1999–2002 and 2007–2008. Purified DNA samples are available from these survey years in a single set from each survey cycle. DNA samples can be obtained and analyzed with survey data from the NHANES 1999–2000 or 2001–2002 or all four years combined (NHANES 1999–2002) and NHANES 2007–2008. The data release cycle for the NHANES during the period in which DNA specimens were collected is described as NHANES 1999–2000, NHANES 2001–2002 and NHANES 2007–2008.

See: http://www.cdc.gov/nchs/nhanes/nhanes99_00.htm, http://www.cdc.gov/nchs/nhanes/nhanes01-02.htm, http://www.cdc.gov/nchs/nhanes/nhanes2007-2008/nhanes07_08.htm for additional details.

Identifiable health information collected in the NHANES is kept in strictest confidence. During the informed consent process, survey participants are assured that data collected will be used only for stated purposes and will not be disclosed or released to others without the consent of the individual in accordance with section 308(d) of the Public Health Service Act (42 U.S.C. 242m). In NHANES 1999–2002 and 2007–2008, a separate consent form was signed by eligible participants who agreed to the storing of specimens for future genetic research. Only participants that consented specifically to future genetic research in 1999–2002 and 2007–2008 will be available for analyses. Genetic variation results will be linked to the requested information from the NHANES public use data file by the Division of Health and Nutrition Examination Surveys (DHANES) staff. All analyses must be done through an NCHS Research Data Center (RDC) approved mechanism to assure confidentiality.

Research Proposals Categories

Note that the following proposal categories differ from those used in

previous announcements for use of NHANES III DNA samples (Thursday, August 8, 2002 [67 FR 51585] and Friday, January 13, 2006 [71 FR 22248].

Category (A): Studies involving the typing of the complete set of NHANES DNA samples (NHANES III, 7,159 samples; NHANES 1999–2002, 7,839 samples; NHANES 2007–2008, 4,615 samples) for proposals that investigate specific research hypotheses that relate tests of selected genes and demographic or demographic and phenotypic data available from NHANES. This category is open for proposals for use of NHANES III, NHANES 1999–2002 and NHANES 2007–2008 samples. A total of ten full sets of samples for each survey will be available for any review cycle. The investigator will specify which DNA bank, NHANES III, NHANES 1999–2002 or 2007–2008, they are requesting as well as the genetic analyses to be conducted on the samples. The investigator will also include in the research protocol an analytic plan that includes a list of NHANES demographic and clinical variables that would be used for the data analyses. The researcher will conduct the genetic analyses of the approved variations on the samples that are labeled with a unique identification number that is not directly linkable to the public use file and therefore, anonymous to the researcher. To analyze these data with the NHANES public use data, the researcher will provide the genetic variation results with the identification numbers to the Division of Health and Nutrition Examination Surveys. The identification numbers will be matched to the requested variables from public use files data by DHANES staff for analyses that must be conducted through the NCHS RDC or its equivalent. Proposals are limited to the testing of 1,000 genetic variations or less. NCHS cannot guarantee that frequencies for all genetic variations can be published due to confidentiality concerns.

After the NCHS has completed the initial quality control assessment, researchers will be given up to six months to conduct a more comprehensive quality assurance review. The timeframe allowed for this review will depend on the number and characteristics of the genetic tests submitted. At the completion of this review, an announcement will be made to the public announcing the availability of the genetic variation results and the opportunity to link these results to other NHANES data for secondary data analysis. The list of currently available SNPs is available at: *http://www.cdc.gov/nchs/nhanes/genetics/genetic_types.htm*.

All samples will be distributed in complete sets of samples of 96 well plates. NHANES III DNA is in the form of crude cell lysates. There will be a total of 7,159 NHANES III samples distributed in a total of 75 plates with an additional four plates of quality control samples. There are 7,839 NHANES 1999–2002 purified DNA samples. These will be distributed into 82 plates with approximately five plates of quality control samples. There are 4,615 purified DNA samples available from NHANES 2007–2008. These will be distributed into 49 plates with approximately three plates of quality control samples.

Note: If the investigator would like to propose a subsample of the full set please contact the Program to discuss feasibility.

Category (B): Additional research using samples already obtained from previous solicitations: Researchers that have obtained NHANES DNA samples from previous solicitations and have sufficient DNA left may request to do additional tests on the remaining DNA. Proposals under this Category must be submitted and approved before the DNA samples were scheduled to be destroyed or returned. The investigator will specify the genetic analyses to be conducted on the samples. The investigator will also include in the research protocol an analytic plan that includes a list of demographic and clinical variables that would be used for the data analyses.

Category (C) Proposals involving whole-genome genotyping of DNA samples: All proposals for whole-genome genotyping of more than 1,000 genetic variations must provide funding for the testing to the NHANES program so that the testing can be done under an NHANES contract. If funding is available, CDC intends to provide whole genome-genotyping data from NHANES III and NHANES 1999–2002 samples. These data will be available for secondary data analysis.

NHANES III DNA Samples

The laboratory will distribute aliquots of crude cell lysates. DNA concentrations vary and are estimated to range from 7.5–65 ng/μL with an average of approximately four micrograms in 100 μL. Each 96 well plate will be bar-coded and labeled with a readable identifier. Quality control samples (approximately 384 samples) will be sent at no charge, either inserted with the NHANES samples or in separate plates, as blind replicates and/or blanks. Description of these samples and cost has been previously published *see:* (Friday, January 13, 2006 [71 FR 22248]).

NHANES 1999–2002 and 2007–2008 DNA Samples

The laboratory will distribute aliquots of purified DNA of normalized concentrations of 50 ng/μL whenever possible. Some samples may fall below this threshold. Forty microliters of each specimen will be supplied. The amount of DNA in each aliquot may vary but will be on average approximately two micrograms. Each 96 well plate will be bar-coded and labeled with a readable identifier. Quality control samples (NHANES 1999–2002, approximately 480 samples; NHANES 2007–2008, approximately 288 samples) will be sent at no charge, either inserted with the NHANES samples or in separate plates, as blind replicates and/or blanks.

Proposed Cost Schedule for Providing NHANES DNA Samples

Costs are determined both for NCEH and NCHS and include the physical materials needed to process the samples at the NCEH laboratory, as well as the materials to process the requests for samples at NCHS. These costs include salaries of the staff needed to conduct these activities at each Center. The fee is estimated to cover the costs of processing, handling, and preparing the samples. Technical panel travel and expenses are based on the panel meeting twice a year. The space estimate is based on acquiring storage and sample aliquoting space in the laboratory. The cost per samples for NHANES III samples is the same as published in 2006 (Friday, January 13, 2006 [71 FR 22248]) and the cost for NHANES 1999–2002 and NHANES 2007–2008 are the same as published in 2007 (Thursday, October 18, 2007 [72 FR 5904]).

Total costs	Cost per sample full set, 99–02 & 07–08	Cost per sample partial set, 99–02 & 07–08 (special request)	Cost per sample full set, NHANES III	Cost per sample partial set, NHANES III (special request)
Materials	$0.89	$2.19	$0.85	$1.90
Labor	4.60	25.30	3.30	22.00
Application review and other administrative expenses	0.54	3.09	0.35	2.69
Space	0.17	1.12	0.13	0.97
Subtotal	6.20	31.70	4.63	27.56
NCHS overhead (18 percent)	1.12	5.71	0.83	4.97
Subtotal	7.32	37.41	5.46	32.52
CDC/FMO overhead (0.9 percent)	0.66	3.37	0.49	2.93
Total sample cost per sample	7.98	40.78	5.95	35.45
Total cost per proposal	99–02: $63,555 07–08: $36,828	NA	42,596.36	NA
Total cost per Category B proposal: for data handling	99–02: $6,255 07–08: $3,683	[1]	4,260	[1]

[1] 10 percent of original cost of samples.

Procedures for Proposals

The investigator should follow these instructions for preparation of proposals. Once testing is complete the IRB protocol is closed and the project is transferred to the Research Data Center (RDC). The content of the IRB protocol becomes the RDC project description and the project is covered by the umbrella RDC IRB Protocol. Protocols must be written using the outline below. All proposal categories need a full research proposal for review. In addition to the cover page, the research proposal should contain the title of the research project, the name, address phone number and E-mail address of the lead investigator along with the name of the institution where the genotyping will be conducted, and the category of proposal (A, B or C) submitted. Office of Human Research Protections assurance numbers for the institutions engaged in the research project should be included. CDC investigators need to include their Scientific Ethics Verification Number. E-mail submission of the proposal is encouraged.

The proposals should be a maximum of 20 single-spaced typed pages, excluding figures and tables, using ten cpi type density. Please use appendices sparingly. If a proposal is approved, the title, specific aims, name, and phone number of the author will be maintained by NCHS and released if requested by the public. Unapproved proposals will be returned to the investigator and will not be maintained by NCHS.

Since the number of sets of DNA is limited, proposals will be reviewed by the technical panel and then will be reviewed by a secondary review panel composed of CDC officials. The technical panel will determine if the proposal is technically sound and if so, the technical panel will rank the proposal on a scale of 0–100. Proposals that are rejected will not be scored.

Applications will also be reviewed by an internal Secondary Review Committee which will perform a programmatic review based on the results of the peer review for technical merit. The Secondary Review Committee considers the scientific and technical merit results from the first level of review, important programmatic considerations such as program priorities, program relevance, and other criteria germane to this announcement and to CDC. The Secondary Review Panel will be comprised of senior CDC scientists. Approved proposal will then be reviewed by the CDC/NCHS Ethics Review Board (ERB) to ensure appropriate human subjects protections are provided, in compliance with 45 CFR 46.

Category A, B and C Proposals should include the following information:

(1) *Cover sheet:* See Example in Sample Proposal on *http://www.cdc.gov/rdc/B3Prosal/PP320.htm* Also include, the name of the institution where the genotyping will be conducted, which category, and Office of Human Research Protections assurance numbers for the institutions engaged in the research project should be included. Plus, CDC investigators need to include their Scientific Ethics Verification Number.

(2) *Abstract:* Please limit the abstract to 300 words.

(3) *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.

(4) *Background and Public Health Significance:* (A) Describe the public health significance of the proposed research. (B) Discuss how the results will be used. Analyses should be consistent with the NHANES mission to assess the health of the nation. The Panel will ensure that the proposed project does not go beyond either the general purpose for collecting the samples in the survey or the specific stated goals of the proposal.

(5) *Design, Method, and Output:* (A) *Research Design and Methods:* Describe the analytic and statistical methods to be employed. Include power calculations. For all proposal categories, include a detailed description of the laboratory methods. The characteristics of the laboratory assay, such as reliability, validity, should be included with appropriate references. The potential difficulties and limitations of the proposed procedures should also be discussed. Address adequate methods planned for handling and storage of samples. (1) Category A proposals will be provided with approximately 480 quality control samples at no additional cost. Approved projects must run these quality control samples and submit the results from the NHANES DNA samples. (2) Category B proposals will be required to use residual quality control samples. The proposal should contain a discussion of additional quality control procedures the laboratory will use to assure the validity of the test results. Address adequate methods planned for handling and storage of samples. (B). *Output:* Please describe any output that you would like to take out of the RDC: Please be detailed as this section helps

the Review Committee assess disclosure risk. Include detailed examples of table shells, models, and/or graphs. How will you present the results of this project? (C). *Data Dictionary:* Includes (1) NCHS Restricted Data Dictionary (2) NCHS Public Use Data Dictionary (3) Non-NCHS Data Dictionary *see: http://www.cdc.gov/rdc/B3Prosal/PP323.htm.* The appropriateness and adequacy of the methodology proposed to reach the research aims as well as the appropriateness of using the NHANES a complex, multistage probability sample of the national population, to address the goals of the proposal will be assessed.

(6) *Additional information for NHANES:* (A) *Discussion Regarding the Race/Ethnicity Variables:* If the research is limited to specific race or ethnic groups (only applicable for a subsample request) or if information about the race or ethnicity of the subjects is requested, indicate the reason for analyzing race/ethnicity and how the results will be interpreted. Discuss the potential for group harm. (B) *Clinical Relevance of Research Findings:* The samples under this Plan are available for genetic research, not genetic testing. Therefore, it is the intent of the program to approve only those proposals that would yield meaningful research, but not clinically relevant information for the participants. Researchers should justify that the test results should not be reported to the subjects. (C) *Period of Performance:* Specify the project period. The period may be up to three years. At the end of the project period, any unused samples must be returned to the NHANES DNA Specimen Bank in accordance with instructions from the Division of Environmental Laboratory Science. Extensions to the period of performance may be requested. (D) *Funding:* Include the source and status of the funding to perform the requested laboratory analysis. Investigators will be responsible for the cost of processing and shipping the samples (*See table*). Also, in general information for RDC.

(7) *References*

(8) *Résumés/CV:* Please include a 2-page CV for each member of the research team in this document (not as attachments).

Public Availability of Data

Genetic test results from all studies using NHANES DNA samples will be made available to the public for secondary data analyses. After the NCHS quality control review is completed, researchers will be given up to six months to conduct a more comprehensive quality assurance review. The final quality control review timeframe will be negotiated between the researcher and the NCHS Project Officer and will depend on the number and characteristics of the genetic tests submitted. This time for final review is provided before the announcement is made to the public that the test results are available for submission of proposals for secondary data analyses. The list of currently available genotypes will be outlined on: *http://www.cdc.gov/nchs/nhanes/genetics/genetic_types.htm.* Proposals for secondary data analyses linking NHANES public use data with genetic variation data will be reviewed by the Research Data Center on a rolling basis see: *http://www.cdc.gov/rdc/B3Prosal/PP320.htm* for proposal guidelines.

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

In NHANES III, NHANES 1999–2002, and NHANES 2007–2008 race/ethnicity was derived by combining responses to questions on race and Hispanic origin. For NHANES III, These categories are defined as non-Hispanic white, non-Hispanic black, or Mexican American. For NHANES 1999–2002, and NHANES 2007–2008, these categories are defined as non-Hispanic white, non-Hispanic black, Mexican American or Other Hispanics. Individuals who did not self-select into these categories were classified as "other". If proposal requests a subsample and excludes one or more race/ethnic groups or a gender, this exclusion must be justified.

CDC is also sensitive to the stigmatization of racial/ethnic specific populations through inappropriate reporting and interpretation of findings. For all proposals that request information on race/ethnicity for the samples selected, the investigator should discuss the reason for analyzing race/ethnicity, how the results will be interpreted, and the potential for group harm.

Submission of Proposals

Proposals can be submitted immediately. The review process will begin approximately 60 days from the publication of the notice and will include all proposals submitted as of that date.

Electronic submission of proposals is encouraged. Please submit proposals to: Geraldine McQuillan, PhD, 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: 301–458–4840, Fax: 301–458–4028 E-Mail: *NHANESgenetics@cdc.gov.*

Approved Proposals

The genetic results will be sent back to NCHS so they can be linked to the requested NHANES III, NHANES 1999–2002 or NHANES 2007–2008 public use data. Analysis will be done in the Research Data Center.

Agency Agreement

A formal signed agreement in the form of a Materials Transfer Agreement (MTA) with individuals who have projects approved and funding has been secured will be completed before the release of the samples. This agreement will contain the conditions for use of the DNA as stated in this document and as agreed upon by the investigators and CDC. A key component of this agreement is that no attempt will be made to link the results of the proposed research to any other data, including, but not limited to, the NHANES public use data sets outside the Research Data Center. Also, the investigator agrees that the samples cannot be used for commercial purposes. A list of genes generated from the testing of the NHANES samples will be made available to the public for potential solicitation of proposals for secondary data analysis after the quality control process has been completed (approximately six months after NCHS receives the genetic variation results). These secondary data analysis proposals must also be reviewed by the ERB.

Progress Reports

A progress report will be submitted annually. CDC/NCHS/ERB continuation reports are also required annually if testing is not completed within a year. An ERB continuation form will be sent to the researcher each year for project update.

Termination of ERB Protocol

At the end of laboratory testing the Ethics Review Board Protocol will be closed. All data analysis will be conducted through the NCHS Research Data Center (RDC). For secondary data analysis project an analytic plan must be submitted to the RDC to set up the analytic data set. *See: http://www.cdc.gov/nchs/r&d/rdc.htm* for guidelines.

Disposition of Results and Samples

No DNA samples provided can be used for any purpose other than those specifically requested in the proposal and approved by the Genetics Technical Panel, the Secondary Review Committee 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 upon completion of the approved project. These results, once returned to NCHS and quality controlled, will be part of the public domain. Genetic test results from all studies using NHANES DNA samples will be made available to the public for secondary data analyses. After the NCHS quality control review is completed, researchers will be given up to six months to conduct a more comprehensive quality assurance review. The final quality control review timeframe will be negotiated between the researcher and the NCHS Project Officer and will depend on the number and characteristics of the genetic tests submitted. Data analyses will be conducted at the NCHS' Research Data Center or similar environment provided by NCHS. Proposals for secondary data analyses are accepted on a rolling basis (*http://www.cdc.gov/nchs/nhanes/genetics/genetic_types.htm*).

Send Requests for Information

Geraldine McQuillan, PhD, 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: *NHANESgenetics@cdc.gov.*

Dated: May 24, 2010.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Procedures and Costs for Use of the Research Data Center

AGENCY: National Center for Health Statistics, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice and request for comments.

Authority: Section 306 of the Public Health Service Act, as amended (42 U.S.C. 242k) and Public Law 103–333.

SUMMARY: This notice provides information about the Research Data Center (RDC) operated by the National Center for Health Statistics (NCHS) within the Centers for Disease Control and Prevention (CDC). The Research Data Center was established in 1998 to provide a mechanism whereby researchers can access detailed data files in a secure environment, without jeopardizing the confidentiality of respondents. Historically, the data files accessed in the RDC have consisted of NCHS survey data and vital statistics. RDC has recently begun accepting data files that were not produced from NCHS survey data. In order to assure that all data files are processed in a consistent manner, the original guidelines for accessing files in the RDC are being reviewed and revised as necessary. As part of the revision process, potential users are being given the opportunity to provide input on how the procedures of the RDC can best serve their research needs. This notice describes how to submit proposals requesting use of the data, mechanisms to access the RDC, requirements, use of outside data sets, costs for using the RDC, and other pertinent topics. We are seeking comments on these procedures and will post the final procedures on the NCHS Web site.

ADDRESSES: Send comments concerning this notice to Peter Meyer, National Center for Health Statistics, 3311 Toledo Road, Room 4113, Hyattsville, MD 20782, or e-mail to *pmeyer1@cdc.gov.*

FOR FURTHER INFORMATION CONTACT: Peter Meyer, telephone 301–458–4375.

SUPPLEMENTARY INFORMATION:

Operational Procedures for Use of the Research Data Center; National Center for Health Statistics; Centers for Disease Control and Prevention

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National Center for Health Statistics Research Data Center Procedures

Background

The National Center for Health Statistics (NCHS) releases and hosts a range of statistical data products on the health and well-being of the nation and its health care system. Statistical tabulations (tables) present data in predetermined categories such as age, race, sex or geographic region that are important to describe health status and trends. In addition, statistical microdata containing health and related variables are published so that outside analysts may conduct original research and special studies to address issues of public health science and policy. Section 308 (d) of the Public Health Service Act and the NCHS Staff Manual on Confidentiality do not permit the release of data that are either identified or identifiable to persons outside of NCHS. In order to preserve privacy and confidentiality, details that might identify or facilitate the identification of persons and entities participating in NCHS surveys and data systems either owned or hosted by NCHS are not released in published data products. Examples of data elements that might be abridged or suppressed to prevent reidentification are geographic identifiers, genetic data, details of sample design, and variables such as age or income that might exist in other databases.

Despite the wide dissemination of NCHS data through publications, Web releases, etc., the inability to release files with these sensitive variables limits the utility of NCHS data for research, policy, and programmatic purposes and sets a boundary on one of the Department of Health and Human Service's goals: to increase our capacity to provide state and local area estimates. In pursuit of this goal and in response to the public research community's interest in restricted data, NCHS established the NCHS Research Data Centers (RDCs), a place where Guest Researchers can access detailed data files in a secure environment, without jeopardizing the confidentiality of respondents. Access for Guest Researchers is regulated by the Confidential Information Protection and Statistical Efficiency Act (CIPSEA) and other Federal statutes. The RDCs provide restricted access to NCHS data and non-NCHS data. Guest Researchers function under the supervision of NCHS employees and are subject to the same provisions of law with regard to confidentiality as NCHS employees. Instructions for developing a research proposal can be found in Appendix II. Special requirements for use of non-NCHS data can be found in Appendix III, Project-Specific Requirements.

Methods to Access Data

Restricted NCHS data or data hosted by NCHS can be made accessible through the RDC. To gain access to these data, Guest Researchers must submit a proposal for review and approval. Once the proposal is approved, Guest Researchers meeting certain criteria are allowed access, under strict supervision, to restricted statistical microdata file(s). There are four modes of access: (1)