The Hispanic Community Health Study/ Study of Latinos (HCHS/SOL)

Supporting Statement Part A – Revised

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Summary of the Hispanic Community Health Study (HCHS)/ Study of Latinos (SOL)

The Hispanic Community Health Study/ Study of Latinos (HCHS/SOL) seeks to determine the prevalence of risk factors for cardiovascular disease among Hispanics/Latinos living in the U.S., and their relationship to cardiovascular morbidity and mortality, compared to U.S. non-Hispanic/Latino populations. In addition, during the study, additional factors that could exert a protective or harmful effect on the cardiovascular system will be identified. The prevalence of these factors (and their relationship to cardiovascular morbidity and mortality) will be compared, to the extent possible, among four different large groups: Mexicans/Mexican-Americans, Puerto Ricans, Cubans, and Central/South Americans. The geographical clustering by country of origin makes it impossible for every group to be adequately represented in each community studied. The prevalence of risk factors for and the presence of other chronic diseases, including asthma, emphysema, chronic obstructive pulmonary disease, sleep disorders, diabetes, dental and periodontal disease, hearing impairment, and neurocognitive impairment will also be compared across communities, ethnic group (to the extent possible), and among other measured characteristics. After the baseline examination, a longitudinal follow-up will serve to identify both fatal and non-fatal cardiovascular and pulmonary events, changes in health status, changes in other underlying chronic diseases, onset of risk factors for the conditions mentioned above, hospitalizations, and all-cause mortality. Nutrition and nutritional practices will also be examined at baseline, and changes to nutrition will also be identified throughout the study period. Finally, special emphasis will be placed on the role of acculturation on the onset or progression of disease. The degree of preservation of traditional practices and nutritional habits versus the degree of incorporation of the North American lifestyle and their impact on health in

general and the onset of specific diseases will be compared among groups.

Four thousand (4,000) men and women, between the ages of 18 and 74 years, will be recruited from each community (a total of 16,000) to participate at a baseline examination and a follow-up telephone call that will take place yearly for the next three years following the baseline examination. The Field Centers are located in San Diego (a consortium of the San Diego State University, the University of California at San Diego and the San Ysidro Health Center, Inc.), Chicago (a consortium of Northwestern University and the University of Illinois at Chicago), New York (Albert Einstein Medical College-Montefiore Medical Center), and Miami (University of Miami). Coordination of methods, instruments, training, and data analysis will take place at the University of North Carolina at Chapel Hill.

1. Justification

A.1 Circumstances Making the Collection of Information Necessary

The objective of this information collection is within the National Heart, Lung, and Blood Institute (NHLBI) mandate described in the Public Health Service Act, Section 421 (42 USC 285b-3) and specifies the provision of "investigation into the epidemiology, etiology and prevention of all forms and aspects of heart, blood vessel, lung and blood diseases, including investigations into the social, environmental, behavioral, nutritional, biological and genetic determinants and influences involved in the epidemiology, etiology and prevention of such diseases." (included).

The Hispanic/Latino population is now the largest minority population in the U.S. with a projected three-fold growth by 2050. Hispanics/Latinos are influenced by factors less commonly found in other U.S. population groups, including changes in diet, activity, community support, working conditions, and health care access, particularly as these changes are associated with immigration from different cultural settings and environments. They are experiencing increasing obesity, higher risk and prevalence of diabetes, and changes in social and behavioral factors with large potential impact on many major chronic diseases. They consist of population groups originating from multiple geographic areas and founder populations, and with residence in the U.S for varying lengths of time, ranging from many generations to less than a year. These differing cultural and genetic backgrounds can have a large potential to influence disease risk.

National data show that U.S. Hispanic/Latino populations overall have lower coronary heart disease mortality rates than non-Hispanics/Latinos, but have an increased prevalence of obesity and diabetes. U.S. Hispanics/Latinos also have a lower incidence of, and mortality from, cancer (all sites) than non-U.S. Hispanics/Latinos. These data also show that some

Hispanic/Latino groups have high asthma burden, with Puerto Ricans having a four-fold higher asthma prevalence than Mexican/Mexican-Americans. Disproportionate numbers of Hispanics/Latinos have fewer economic resources and more may be employed in occupations with exposures that could adversely affect health and increase risk of disease.

If the immigrant Hispanic/Latino populations follow the patterns of most other immigrant groups, their risk of chronic diseases associated with the U.S. lifestyle and culture is likely to increase. Observational data are needed to assess changes associated with immigration and acculturation to living in the U.S., identify those strongly related to disease risk, and determine how best to prevent the risk factor changes which are most harmful to health. Research in differing cultural settings, such as various Hispanic/Latino groups with varying periods of residence in the U.S., can identify differences in risk factor associations not identifiable in more homogeneous U.S. populations. If the risk of some diseases, such as CHD or cancer, is actually lower in Hispanics/Latinos than in non-Hispanics/Latinos, or the risk of other diseases, such as asthma, obesity or diabetes is higher in some Hispanic/Latino groups, identification of factors contributing to these differences will be relevant to both Hispanics/Latinos and non-Hispanics/Latinos.

Hispanic/Latino populations are very much understudied with respect to many diseases. Their projected population growth underscores the need for accurate evaluation on their disease burden and risk. Their disproportionately lower economic status results in significant disparities in health care. Compared to non-Hispanics/Latinos, Mexican-Americans (and for some indices all Hispanics/Latinos) are half as likely to have their hypertension controlled, more than twice as often report no usual health care, have a greater prevalence of reported fair or poor health, and are twice as likely to have no health insurance. Diabetes and asthma appears to be more

prevalent among Puerto Ricans, and occupational exposure put Hispanics/Latinos from lower socioeconomic statuses at higher risk for other lung diseases.

The Hispanic Community Health Study/Study of Latinos, is an extremely comprehensive research study, utilizing questionnaires, measurements of risk factors, identification of disease, and measurement of components of the blood. These measurements will provide the capability to investigate a multitude of hypotheses on the nature, emergence, and risk factors for and causes of various diseases in the Hispanic/Latino population of the United States. The study sample size is large because it is necessary to include each of the major groups of Hispanics/Latinos that reside in the U.S. While most prior research on Hispanics in the U.S. has concentrated on those of Mexican origin, each group has differing cultural and behavioral traditions, differing food, differing reasons for immigration and, from the little information currently available, differing levels of health and risk. Research on one group will not provide answers related to one of the other groups. Thus, we will obtain a better understanding of all-cause and cardiovascular mortality among different Hispanic/Latino groups and obtain estimates of the prevalence of a variety of disease risk factors and health conditions. Longitudinal cohort studies in Hispanic/Latino populations are needed to understand the development of risk factors and disease in these populations, and to apply the knowledge gained for the prevention of disease in this subgroup as well as in the entire U.S. population.

In the long term planning, the study has four analytical components. First, the study sample supports estimates of the prevalence (or mean values) of baseline risk factors for 1) all Hispanics combined in this study; 2) all study Hispanics by community of residence; 3) all study

Hispanics by country of origin; 4) to a limited extent all study Hispanics by community of residence controlling for country of origin; and 5) to a limited extent all study Hispanics by country of origin controlling for community of residence. Secondly, the study sample supports evaluation of the relationships between the various risk factors, demographic factors, and cultural factors collected at baseline. Thirdly, the study sample supports evaluation of factors collected at baseline in relation to the incidence of disease and death that will occur during the follow-up period. Within the current follow-up period, there will be a small number of events (about 100) for broad analysis of risk factors and incidence. In the longer follow-up (proposed but not funded at this time) there will be increasing numbers of events for more detailed and complex analysis. Lastly, the study sample supports the future potential for a re-examination and re-measurement of the same factors collected at the baseline examination. A re-examination of these cohorts is proposed, but not funded at this time, and would provide estimates of factors related to change in the measured characteristics, and would provide the ability, with further follow-up, to estimate the impact on disease and death.

A.2. Purpose and Use of the Information Collection

The purpose of HCHS/SOL is to estimate the prevalence of cardiovascular risk factors, and risk factors for other chronic diseases, as well as the incidence of cardiovascular events (morbidity), cardiovascular mortality and all-cause mortality in a randomly selected sample of men and women who identify themselves as being Hispanic or Latin, representing four different geographic locations in the U.S. The Field Centers are located in San Diego (a consortium of the San Diego State University, the University of California at San Diego and the San Ysidro Health Center, Inc.), Chicago (a consortium of Northwestern University and the University of

Illinois at Chicago), New York (Albert Einstein Medical College-Montefiore Medical Center), and Miami (University of Miami). Coordination of methods, instruments, training, and data analysis will take place at the University of North Carolina at Chapel Hill.

The purpose will be accomplished through the identification, sampling and recruitment of up to 4,000 persons of Hispanic/Latino origin from each of these separate communities for participation in a longitudinal epidemiology study (up to 16,000 persons total, age 18-74). The current contract period is 6.5 years with cohort recruitment and examination scheduled for 3 years. Follow-up of the cohort as well as analysis of baseline data will also take place during this time period. (Timeline attached). Data will be collected in the form of a detailed interview and examination of these study participants including fasting blood tests, a 2-hour oral glucose tolerance test, an electrocardiogram, ankle-brachial pressure measurements, a dental exam, a hearing test, pulmonary function tests, sleep study, neurocognitive tests, and questionnaires procedures to capture health behaviors and risk factors for many chronic diseases. NHLBI will use the results to identify the prevalence of and risk factors (protective or harmful) for diseases, disorders and conditions in Hispanic/Latino populations, and to determine the role of acculturation and disparities in their prevalence and development.

A one-time extensive examination of this population sample of Hispanic residents in the Study communities is scientifically important and has public health and policy implications, with or without repeat examinations. The characterization of this minority population (and its sub-populations by country of origin) is uniquely informative to fill gaps in current knowledge of the health-related beliefs, behaviors, socioeconomic contest, risk factor profile, metabolic phenotypes, self-reported and objectively quantified illnesses. Since information on these attributes is fragmentary or non-existent for this minority group, the one-time testing designed

for this contract period is significant and fully informative contribution to public health. Results will be published in appropriate scientific journals, be presented at scientific meetings and, after full scientific evaluation, will be presented as policy recommendations by NHLBI using public education and health promotion and disease prevention programs. Recommendations for continuation of the study and a repeat examination of the cohort also will take place. The data collection instruments are included in English and Spanish.

A.2.a Baseline Data Collection and Cross Sectional Analysis

The cross-sectional hypotheses can be grouped into broad research areas. These objectives can be accomplished within the funded contract period of 6 ½ years. Below is a small selection of the many research questions related to cross-sectional data only:

Obesity and physical activity:

***Measurements/questionnaires*:** height, weight, waist girth, daily activity by accelerometer, a questionnaire on physical activity and weight loss, type of occupation.

Research questions: How is obesity related to country of origin, length of stay in the U.S., degree of acculturation, type of dietary intake, work on the job, leisure activity, intensity of activity, age and sex? Answers to these questions can help understand the causes of weight gain, and to target weight programs for the various Hispanic groups.

Diabetes

***Measurements/questionnaires*:** reported diagnosis of diabetes, fasting and sugar challenged blood glucose and insulin, hemoglobin A1C.

***Research questions*:** How does the prevalence of diabetes vary by country of origin, acculturation, and obesity? Is diabetes prevalence higher in those with greater acculturation and length of stay in the U.S., and if so, why? What is the degree of association of diabetes with obesity, physical activity, and a glycemic diet? Have participants sought and obtained appropriate health care for diabetes? Is diabetes associated with diseases of the kidney and liver? Since diabetes is a major health

problem in Hispanics, answers to these questions can help in identifying causes, define prevention strategies, and improve medical care.

Hypertension and high cholesterol

***Measurements/questionnaires*:** sitting blood pressure, plasma total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides.

***Research questions*:** How does the prevalence of hypertension vary by country of origin, acculturation, obesity, physical exercise, stress? What is the association between hypertension and life style behaviors including diet, smoking, and access to health care? How does the prevalence of high cholesterol (or other adverse lipids) vary by country of origin, length of time in the U.S., medication use? What are other correlates of an adverse lipid and blood pressure risk profile? Answers to these questions can assist in understanding the etiology of adverse blood pressure and lipid levels in Hispanics, and can provide guidelines for treatment.

Acculturation and health

***Measurements/questionnaires*:** Questionnaires on length of stay in the U.S., retention of Spanish language and customs/behaviors/attitudes from country of origin, retention of food preferences and eating behaviors from country of origin, identification of values with country of origin.

***Research questions*:** How is acculturation related to specific health conditions (cardiovascular, diabetes, kidney, liver, dental, hearing, cognition)? What are the components of the acculturation relationships and how do they help understand the etiology of these diseases? How does acculturation affect health seeking behaviors and access? Answers to these questions can provide understanding on the general observation that acculturation to the U.S. generally worsens aspects of cardiovascular health and diabetes. The consequence of acculturation to other health conditions is mostly unknown and will be explored in this study.

Dental and hearing conditions

***Measurements/questionnaires*:** A dental exam will identify tooth loss, tooth caries and periodontal disease. A hearing exam will identify components of hearing loss.

***Research questions*:** What is the prevalence of dental and hearing conditions by country of origin, length of stay in the U.S. and acculturation? What are the significant correlates of higher prevalence of these conditions? Answers to these questions will provide totally new information on the severity of diseases and conditions and will inform regarding the burden of the conditions, the causes of the conditions, and ways to prevent the conditions from occurring.

Peripheral vascular disease

***Measurements/questionnaires*:** The ankle/brachial blood pressure index will be measured and calculated. This simple non-invasive test measures early atherosclerosis in the peripheral arteries.

***Research questions*:** Are there differences in the prevalence of early atherosclerosis by country of origin, acculturation or length of time in the U.S.? Is atherosclerosis associated with diabetes, obesity, cigarette smoking in this population? Answers to these questions will provide evidence regarding the differential development of disease in Hispanic subgroups and with acculturation, providing information to understand the impact of the U.S. life style on immigrant groups.

Cognitive impairment

***Measurements/questionnaires*:** There will be performance measures of cognitive impairment involving memory and decision making.

***Research questions*:** How is the degree of cognitive impairment related to age, sex, county of origin, length of stay in the U.S.? How is the degree of cognitive impairment related to vascular parameters such as blood pressure, ankle-brachial index, lipid levels, kidney impairment or other factors? Cognitive impairment is a significant component of disability in advanced age and current research supports a vascular component of etiology.

Liver and kidney diseases

***Measurements/questionnaires*:** Blood measures for the various hepatitis types, creatinine, liver enzymes, iron, and urine values of albumin and creatinine.

***Research questions*:** How does the prevalence of hepatitis types vary by country of origin, length of stay in the U.S. and acculturation? What is the prevalence of kidney impairment and how does this vary by country of origin and other co-factors of cardiovascular disease. Information on the degree of kidney and liver diseases will provide estimates of the burden of disease, and strategies for preventing and treating these conditions.

A.2.b Longitudinal Data Collection and Analyis

The longitudinal portion of this study has two components. The first component, which is funded in the current 6 and ½ year period, is to contact individuals annually by telephone (or in person if unable to contact by phone), to ascertain current household location and contact information, to conduct a brief health history, and to identify any hospitalizations that may have taken place in the previous year. When these hospitalizations are identified, the study (with signed permission from the participant) will obtain the medical record from the hospital, will abstract relevant information and will provide a validated diagnosis for the disease and this will

become part of the study data base. This process will provide identification of incident occurrences of coronary heart disease, stroke, heart failure, and exacerbations of chronic obstructive lung disease and asthma. In the time frame of this funded portion (6 ½ years) the expected average follow-up for incident disease will be 3 ½ years. The number of validated cases of myocardial infarction or coronary heart disease death in this follow-up time period is estimated to be around 100. This is a small number, but will provide initial estimates of incidence and of relative risk for major risk factors in the total population. The statistical strength of a longitudinal study is in future long term follow-up. An additional follow-up period, adding at least 5 additional years of follow-up will provide extensive endpoint events to be able to analyze baseline characteristics in their association to future disease. As described earlier, this will require future funding.

The second component, not funded in the current cycle of funding, is a re-examination of the entire cohort. The scientific objective is to re-examine the population approximately six years after their first baseline examination. This will provide additional data on change in the characteristics under consideration, and will allow analysis of factors relating to either beneficial or adverse changes in the factors identified at baseline. For all of the research groups listed above, there are questions related to the etiology of change in these risk factors and their consequences to disease. This second component will be proposed, reviewed, and subject to the same scientific review process as occurred during the initial review and approval.

A one-time, extensive examination of this population sample of Hispanic residents of the HCHS study communities is scientifically important and has public health and policy implications, even in the absence of repeat examinations. The characterization of this minority population (and its subpopulations by country of origin) is uniquely informative to fill the gaps

in current knowledge of the health related beliefs, behaviors, socioeconomic context, risk factor profile, metabolic phenotypes, self-reported and objectively quantified illnesses. Since information on these attributes is fragmentary or non-existent for this minority group, the one-time testing designed for this study represents a significant and fully informative contribution.

An additional justification for the testing described above is that it serves as a baseline description that enables the ascertainment of the study outcomes as newly developed, incident events. In turn, the various baseline measurements incorporated into the examination permit the estimation of the antecedent factors that influence the population's susceptibility to these health outcomes. Risk factors as well as protective factors can thus be identified for this population, over a range of modifiable beliefs, behaviors, and phenotypes.

The baseline and longitudinal assessments described above represent the measurements and scientific inquiries that led to effective risk estimation, to health policies and clinical guidelines for priority health issues in other population groups. Such information is not available at this point for Hispanics/Latinos resident in the United States.

A.3. Use of Information Technology and Burden Reduction

The HCHS/SOL will use state-of-art data entry and management systems which maximize data accuracy and minimize respondent burden using a computer assisted personal interview (CAPI) approach. The data entry system displays screens that resemble paper forms. The data collector reads the items from the screen, performs the measurement or queries the participant, and keys the response into the computer. As data for a field are entered, they are edited by the system. The values failing the edit checks cause an error message to be displayed and prevents further entry until the problem is resolved. The data collector can correct the value,

confirm it, or flag it as "questionable" and in need of further investigation. In addition to collecting and editing the data, the system permits users to enter text into an electronic "post-it notes" attached to any field as needed. Automated skip rules rapidly direct the interviewer to the relevant sections of the interview for the particular respondent and provides for very rapid interviewer action, thus lessening the respondent burden.

A.4. Efforts to Identify Duplication and Use of Similar Information

There is no duplication of effort or similar information available because the HCHS/SOL cohort is unique. The HCHS/SOL is the first and largest study to investigate disease prevalence in a standardized manner across four Hispanic/Latino groups in the United States. It includes research components that are being employed for the first time in an adult Hispanic/Latino population including a cross-sectional comparison of the prevalence of cardiovascular risk factors among different Hispanic/Latino groups, a longitudinal component, all-cause mortality rate across groups, assessment of cardiovascular and pulmonary causes of death, a diversity of acculturation instruments, assessment of peripheral arterial function, dental examination, and hearing test and, thus, does not duplicate previous or ongoing research in this population.

Previous large epidemiological studies which have included Hispanics/Latinos in their populations include the current National Health and Examination Survey (NHANES), the previous Hispanic Health and Nutrition Examination Survey (HHANES), and the Multiethnic Study of Atherosclerosis (MESA), the San Antonio Heart Study, and the Corpus Christi Heart Program. NHANES consists of a cross-sectional analysis of a diversity of health aspects and examinations, and does not include a longitudinal component. The MESA included only one Hispanic group of Mexican/Mexican-American ancestry. In addition, differences in prevalence

of risk factors and incidence of other diseases besides cardiovascular disease in the U.S. Hispanic/Latino population have not been fully recorded. Finally, given cultural, political and socioeconomic differences (both in their countries of origin and in the U.S.), a study able to compare and follow a diversity of Hispanic/Latino groups is needed. In addition, the current Latin American immigration patterns are different from twenty years ago, and the Central and South American migration to the U.S. has changed the demography of Hispanics/Latinos in the United States, and an assessment of the health of the U.S. Hispanic/Latino population needs to include them. Finally, the San Antonio Heart Study and Corpus Christi Heart Program only focus on Mexican Americans in Texas and do not offer the breadth that the countries of origin provide in the HCHS/SOL.

Both the cross-sectional and the longitudinal components will provide critical information and are necessary for the aims of this study. The cross-sectional component will provide information to gauge prevalence and cross-sectional associations. The longitudinal component will provide information on causes of change in risk factors and the consequences in relation to incident disease. While the cross-sectional component is similar to NHANES, there are important differences. NHANES is not collecting data with this sample size for the various Hispanic subgroups. NHANES is not collecting the intensive information on Hispanic acculturation and all of its components. NHANES is not collecting information on sleep, physical activity, peripheral vascular disease, and other parameters important for this study. The NHANES is not designed to do follow-up of participants for a clinical re-examination or for incidence of disease.

The unique features of this study (as described above) do not exist in another study. This information collected in HCHS/SOL will further our understanding of the development of

cardiovascular and other health conditions in Hispanic/Latino populations and will be used to recommend targeted and culturally appropriate health promotion and disease prevention approaches.

A.5. Impact on Small Businesses or Other Small Entities

Physicians and other health care providers, hospitals, nursing homes and other long-term care facilities constitute the only small business burdened by the HCHS/SOL. They are requested to provide medical information on selected patients identified by the study. These requests are limited only to essential information needed to determine the presence of disease events, cardiovascular conditions, pulmonary conditions, or to clarify the cause of death. This information collection will not have a significant impact on these small entities.

A.6. Consequences of Collecting the Information Less Frequently

Data collection will take place once at the baseline visit and during one telephone call two weeks after the baseline examination to collect 24-hour dietary recall information. Participants will be contacted annually for three more years via telephone to ascertain cardio-pulmonary related events and hospitalizations. In the case of death, the participant's next of kin or primary physician will be contacted to confirm information obtained from death certificates. Therefore data from an individual participant might be collected up to five times throughout the duration of the study. If data are collected less frequently, relevant information about cause and circumstances of death, changes of health status, number and reasons for hospitalizations and visits to the emergency room, and tracking those participants who would move from their original geographic location will be missed.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.

There are no special circumstances related to the information collection.

A.8. Comments in Response to the **Federal Register** Notice and Efforts to Consult Outside Agency

A copy of the **Federal Register** notice, dated July 11, 2007, wherein public and affected agencies' comments were solicited is included. No public comments were received during the 60-day solicitation.

The HCHS/SOL initiative was developed by the Division of Prevention and Population Sciences in response to a working group assembled on July 31-August 1, 2003, entitled "Epidemiologic Research in Hispanic Populations: Opportunities, Barriers, and Solutions", whose objectives were to identify research questions, barriers to research, and methodological solutions to research problems related to the study of cardiovascular, lung, blood and sleep disorders in Hispanics. The recommendations were to establish a multi-center study with sufficient sample sizes with populations selected in diverse regions of the country. The workshop report is included.

Epidemiology Research in Hispanic Populations: Opportunities, Barriers and Solutions (held on July 31- August 1, 2003)

Co-chairs of the working group
Amelie Ramírez, Dr. P.H., Baylor College of Medicine, Houston, TX
Michael Stern, M.D., University of Texas Health Science Center, San Antonio, TX

Members
Ronald J. Angel, Ph.D., University of Texas at Austin, TX
Sharon Brown, RN, Ph.D., University of Texas at Austin, TX

Felipe González Castro, Ph.D., Arizona State University, Tucson, AZ
David B. Coultas, M.D., University of Florida, Jacksonville, FL
Carlos Crespo, Dr. P.H., State University of New York, Buffalo, NY
Helen Hazuda, Ph.D.,University of Texas Health Science Center, San Antonio, TX
Jean MacCluer, Ph.D., Southwest Foundation for Biomedical Research, San Antonio, TX
Kyriakos Markides, Ph.D., University of Texas Medical Branch, Galveston, TX
Lucina Suárez, Ph.D., Texas Department of Health, Austin, TX
Greg Talavera, M.D., MPH, San Diego State University, San Diego, CA
Katherine Tucker, Ph.D., Tufts University, Boston, MA

8.1 Scientific Review

The scientific merit of this study was reviewed at many steps including the final review by the Advisory Council of the NHLBI. The National Heart, Lung, and Blood Advisory Council met on October 21, 2004, and discussed Hispanics in America and their current and future health problems. The Council considered these data to be important for addressing health burdens in America. The Council review of this study, which includes attention to both the scientific merit and the total cost, was conducted by scientists at the highest level, including among others, a professor of epidemiology, a chief of a division of cardiology, the editor-in-chief of the New England Journal of Medicine, a dean of a nursing school, a professor in a department of medicine, a professor of internal medicine, and a professor of preventive medicine.

A copy of the relevant minutes from this meeting and a roster of Council members are included. (Council-Oct.04.pdf)

The HCHS/SOL Observational Study Monitoring Board (OSMB) met on June 22, 2007,and will meet annually during the course of the study to advise the NHLBI to monitor study progress and performance and to consider issues related to participant safety and privacy. At the June 22, 2007 meeting the OSMB reviewed and approved the HCHS/SOL informed consent, examination protocol and interview questionnaires. Minutes from the OSMB meeting

are included. The members are:

Odilia Bermúdez, Ph.D. 617-556-3183
Tufts University

Enrique Caballero, M.D. 617-732-2485
Joslin Diabetes Center

Hannia Campos, Ph.D. 617-432-0100
Harvard University School of Public Health

Gustavo Cruz, D.D.S. 212-998-9989
New York University

Judy Dubno, Ph.D. 843-792-7736
Medical University of South Carolina

Esteban González Burchard, Ph.D. 415-514-9677
University of California at San Francisco

George Howard, Ph.D. (Chair) 205-934-4905
University of Alabama at Birmingham

Martha Medrano, M.D. 210-567-0963
University of Texas Health Sciences Center at San Antonio

Anne Newman, M.D., M.P.H. 412-383-1871
University of Pittsburgh

A.9. Explanation of Any Payment or Gift to Respondents

Participants will receive a lump sum incentive in the amount of $75 to cover expenses associated with participating in the clinic examination including child care and transportation (gas, tolls, parking, public transit).

A.10. Assurance of Confidentiality Provided to Respondents

All HCHS/SOL Principal Investigators and their institutions have agreed to comply with the Federal Privacy Act as part of their contractual agreement with the NHLBI. The contract stipulates that research involving human subjects cannot be conducted until (1) protocol

has been approved by NHLBI, (2) written notice of such approval is provided by the Contracting Officer, and (3) completed Form SF-310 certifying Institution Review Board (IRB) review and approval of the protocol. As individual field centers and the Coordinating Center approach their respective IRB approval expiration dates, well established mechanisms at each institution are set in motion for timely renewal submissions to occur. Updated IRB approvals are filed with the Coordinating Center for review by the NIH and the Study.

A.10.1 Human Subjects Protection

Participation is this study is voluntary. The contract stipulates that research involving human subjects is subject to an annual review to be submitted each year. Copies of the Institutional Review Boards for each field center and the Coordinating Center indicating approval of the study are included. The consent forms in English and Spanish describe the study to the participants, inform them of the risks and benefits of procedures and where to obtain information about the rights of research subjects (included). Additionally the HCHS/SOL Observational Study Monitoring Board annually reviews any issues involving human subjects protection, and participant burden and safety.

A.10.2 Field Center Security and Confidentiality

Field Center staff is trained in procedures for insuring confidentiality of participant information. Paper records will be kept in secure storage and when no longer useful, will be discarded based on center-specific security protocol. The data management system provides a high level of confidentiality for the machine readable information. Each user of the system has a password that is required to access the system. All files are encrypted to prevent unauthorized

access to the data using other software. In publications and internal study reports, the individual identities of participants and respondents will not be disclosed and data will be reported only in aggregate.

A.10.3 Privacy Act

Information obtained from the study will be included in the Privacy Act System of Records 09-25-0200, "Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD," as published in the Federal Register, Vol.62, No.66/Monday, April 7, 1997, pp. 16596-16602. (included).

Individuals will be informed that they may refuse to participate in specific procedures or the entire examination and that their refusal will not result in any loss of benefits to which they might otherwise be entitled, nor will it adversely affect any medical care. This is stated in the Informed Consent.

Data will only be made available to persons performing statistical analysis following NIH limited access data use policies. If outside consultants or investigators with offices outside the study site need access to the data for publications, a data release will be prepared with no personal identifiers included. All investigators maintain data security and confidentiality in accordance with their Institutional Review Board agreement. The Principal Investigators maintain data security and confidentiality in accordance with guidelines of the NIH.

A.10.4. Field Center Data Management System

Data confidentiality and security are applied at all levels of data acquisition, transfer and storage, for all study agencies, from field centers to the coordinating center. The password controlled access to the study equipment and the data management system (DMS) is the initial level of security. All data collected at the field centers and in hospital record rooms are encrypted by the system and can only be decrypted for display on-screen by authorized study personnel. Personal identifiers are collected on separate forms (and transferred as separate, encrypted records). Should paper data collection forms be used they will be retained at secure locations at the field centers until the Steering Committee acts on recommendations from the Coordinating Center to dispose of such records (e.g., incremental data closure). The secure storage and disposition of hard copy records at field centers will follow institutional procedures at each site.

A.10.5. Coordinating Center Security and Confidentiality

The DMS server is housed at the Coordinating Center and exclusively managed by Coordinating Center personnel. Measures to ensure the security of the data include: restricting access to users with valid IDs and passwords; using a firewall to restrict access to the web server and to shield the UNC Coordinating Center LAN from web users; using the secure sockets layer standard to provide encryption and user authentication. All data transferred to the Coordinating Center is stored, processed, and analyzed within the Coordinating Center office suite, with access to office space containing data controlled through locked doors. Access to computer data files is controlled by passwords released only to the Coordinating Center personnel who use such files. In addition, data files with personal identifiers (and sensitive information per designation by a study's Steering Committee) are encrypted. As standard practice, output mailed to a field

center identifies participants only by ID number. No individually identifiable information is distributed by the Coordinating Center to any study agency other than the originating field center. Printed material containing confidential information is discarded through supervised loading, transportation, and storage using a chain of custody control process, until the material can be recycled into paper pulp. All Coordinating Center staff are required to complete a confidentiality certification procedure upon employment.

Data collected from participants in this study will be stored in encrypted form in the database and maintained in a way that separates personal names and address from the clinical information and questionnaires. Participant data will be de-identifed in a manner that complies with NIH guidelines for security and confidentiality. Only the originating field center investigator and the coordinating center have access to personal information in order to provide individual reporting of results and referrals back to the participant. Data stored at the coordinating center is maintained in accordance with an NIH approved information technology system security plan. The coordinating center on behalf of the study investigators in this multi-site study will apply for a Certificate of Confidentiality from DHHS so that the information is further protected under those statutes. Only information mandated by law (e.g. instances of child abuse or neglect, communicable diseases, etc.) would be reported to outside public health agencies or other explicitly authorized authorities. The study will, with permission of the participants, use identifying data to link to the National Death Index and possibly other medical databases. In this process, the data will be provided and linked using the data security provisions provided by these systems.

A.10.6. Coordinating Center Data Management and Computing

Data is retrieved from the study database and converted into SAS files on a regular schedule (e.g., monthly). Statistical computing is done using SAS software by well-trained, dedicated statistical programming staff, using a well-established statistical computing request system that has proven itself through use with many long-term, multi-center research projects managed by the Coordinating Center. This system includes thorough documentation of requested computing, programming standards, naming conventions for datasets, programs and program results, inventorying and tracking of computing requests, procedures for program review, and permanent archival of completed programs, results, and datasets.

A.10.7. Distributed Data Sets

The coordinating center will produce limited access datasets which meet current guidelines (see http://www.nhlbi.nih.gov/resources/deca/policy_new.htm) for the study investigators after closure checks are performed on each of the yearly baseline examination cohorts. Data sets distributed under this policy include only "limited access data", i.e., records with personal identifiers and other variables that might enable individual participants to be identified, such as outliers, dates, and study sites, removed or otherwise modified. Data sets are only distributed to qualified researchers who agree in advance to adhere to established policies for confidentiality and distribution. Identifiable information is never released under the limited access data set policy. During the funding period for the study, limited access to the data is granted only to the participating investigators at the field centers. No later than 3 years after the end of the examination cycle, or two year after the end of follow-up whichever comes first, a closed limited access data file and supporting documentation will be sent to NHLBI.

A.11. Justification for Sensitive Questions

Although providing the Social Security Number is not required for participation, voluntary disclosure of this information is asked from participants with the purpose of tracking death-related information from the National Death Index and/or their local hospitals and the State Departments of Health. Participants are assured that declining to provide this information will not alter in any way their ability to participate in the project.

Alcohol consumption will be ascertained since studies have suggested that moderate levels of alcohol use may be protective for coronary heart disease.

Cognitive function questionnaires are being used to request information to assess the participants' memory. These data are essential in characterizing the severity and sequelae of stroke. These data are also necessary for research into the causes of dementia.

Current medication use is being determined since most blood chemistry values are modified by pharmacologically active drugs. Thus, knowledge of the use of prescription as well as over-the-counter medication is required to interpret the blood chemistry values. In addition, several medications are modifiers of onset and progression of clinical events (e.g. aspirin, beta blockers), and will be used as covariates in analyses. Information on use of anti-hypertensive and diabetic medications are necessary to assess whether a participant has either of these conditions.

A.12. Estimates of Hour Burden Including Annualized Hourly Costs

The estimates for procedure and interview burden are based on previous experience in prior studies using the same procedures, and on staff volunteers pre-testing interview forms.

(see

Table A.12.1
ESTIMATE OF RESPONDENT BURDEN
HCHS/SOL

Type of Response	Number of Respondents	Number of Responses	Time per Response in Hours	Total Burden Hours
a. Recruitment contacts	22,369	1	0.08	1,790
b. Household enumeration	4,191	1	0.17	712
c. Telephone contact to set up appt	6,667	1	0.08	533
d. Appointment Confirmation	6,667	1	0.08	533
e. CLINIC EXAM				
e1. Procedures	5,333	1	3.67	19,572
e2. Questionnaires	5,333	1	2.75	14,666
f. Participant Telephone Interviews				
24-hour Dietary Intake Recall	5,333	1	0.67	3,573
Follow-Up Call	5,333	1	0.50	2,667
			Subtotal	44,046
Non-participant components[1]				
a. Physician, hospital and nursing home contacts for outcomes ascertainment (total=1,254)	Deaths: 60 CHF: 90 Stroke: 132 CHD: 650 COPD: 210 Asthma: 112	1	0.50	627
b. Informant contact	30	1	0.50	15
c. Focus Groups	81		1.5	121.5
			Subtotal	642
			Grand total	44,809.5

SeeTable A.12.3 for detailed breakdown of individual assessment times.)

1Annual burden is place on physicians and health care providers and respondent relatives/informants through request for information which will help in the compilation of the number and nature of new fatal and non-fatal events.

Table A.12.2
Annualized Cost to Respondents

Type of Respondents	Total Burden Hours	Hourly Wage Rate	Respondent Cost
Participants	44,046	15.00	$660,690
Physician/hospital/ nursing home contact	627	55.00	$34,485
Informant Contact	15	15.00	$225
Focus Groups	81	15.00	$1,822.50
			Total $ 697,222.50

Table A.12.3
Estimates of Administration Time Burden for Examination and Questionnaires

Exam Procedure, fasting status specification (F)	Estimated time (minutes)
Fasting block	**80**
Reception, informed consent, change clothes, urine specimen	30
Anthropometry (F)	08
ECG (F)	15
Seated BP (F)	11
Phlebotomy (F), Glucose load	16
2-hour glucose load, snack	**12**
Procedures, flexible sequence	**81**
Ankle brachial SBP	17
Audiometry + HHE questionnaire	22
Lung function	15
Oral examination + verification of screening status	20
Change clothes	07
Blocks of interviews, flexible sequence: A	**45**
24-hr dietary recall, supplements	
Blocks of interviews, flexible sequence: B	**28**
Alcohol	02
Dietary behavior	03
Economic background	02
Health care use	04
Hearing Hx	04
Medical Hx	07
Medication & Supplement use	06
Blocks of interviews, flexible sequence: C	**44**
Neurocognitive	16
Occupation	07
Oral Health	05
Personal identifiers	07
Personal information	09
Blocks of interviews, flexible sequence: D	**43**
Physical activity	05
Respiratory Hx	09
SF-12 Health Status	05
Sleep Hx	06
Social Network	02
Sociocultural	07
Tobacco use	03
Weight Hx	02
Well Being	04
Visit Termination	**20**
Exit interview	10
Sleep & activity monitoring instructions and tracking	10

Total Examination and other procedures time	**220**
Total Questionnaire interview time	**165**

The annualized cost to the participants consists of the cost of their time for which no remuneration is given. Assuming $15 per burden hour for participants and informants and $55 for physicians and other professional health care respondents, the estimated annual cost for time is $149,415.

A.13. Estimate of Other Total Annual Cost Burden to Respondents or Record-keepers

There are no other total annual costs which apply to respondents or record keepers. There are no capital costs, operating costs, or maintenance costs to report.

A.14. Annualized Cost to the Federal Government

The Hispanic Community Health Study/Study of Latinos is run by contractors. At the same time, there are NHLBI staff contributing to the study. The average annualized cost to the U.S. Government for the information collection in the HCHS/SOL is $10,561,179 per year. This is itemized in Table 14.1 The annual budget for each year currently approved for funding by NHLBI is attached. <budget.response 1.24.08.xls> This funding is committed by the budget office of the NHLBI, and extends for a six and one-half year period. This funding provides for the recruitment process, the baseline examination and all of its components, and ascertainment of hospitalized disease events for cardiovascular and lung diseases for an average of 3 ½ years. This will provide sufficient number of major cardiovascular disease events for global estimates of incidence and relationships with common risk factors. To provide appropriate stewardship of the government's funds, however, the NHLBI establishes a review process before future funds are awarded for continuation of projects. A renewal of the funding of this project, i.e. funding beyond the 6 ½ years, will again require presentation of progress to various review committees,

including the Advisory Council of the NHLBI described above. Thus, while the NHLBI has committed 6 and ½ years of funding to the study, to provide appropriate oversight of federal funds, future funding is not committed until appropriate review and approval is complete.

A.14.1 Average Annualized Cost to the Federal Government

	Personnel	Equipment	Subcontract	Other	Overhead	Total
HCHS/SOL Examination Centers and Coordinating Center	$4,540,264	$33,427	$2,599,773	$977,614	$2,410,101	$10,561,179

Table 14.1 represents average annualized costs for the 6 ½ year duration of the contract period. The annualized cost of monitoring the project by the National Heart, Lung and Blood Institute is estimated at $175,000.

A.15. Explanation for Program Changes or Adjustments

This is a new information collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

The HCHS/SOL staff will collect the information after obtaining OMB approval. The Coordinating Center computing staff will then analyze the collected information in a timely manner after the necessary data editing has been done, and after the data quality control procedures have verified that collection procedures operated properly. The following timetable for data collection and analysis, in terms of the time elapsed following OMB approval, is presented in Table A.16-1.

Table A.16-1 HCHS/SOL Time Schedule

Activity	Time elapsed after OMB approval	
	Start	*Finish*
Participant contact and appointment scheduling	1week	36 months
Data Collection (Exams)	1 month	36 months
Primary Analysis	12 months	60 months
Publication and Secondary Additional Analysis	24 months	60 + months

To achieve the ultimate goal of determining policy recommendations for cardiovascular disease prevention, the intermediate goal is to present statistical results by publishing in scientific journals (e.g. New England Journal of Medicine, Journal of the American Medical Association, Circulation, Journal of Chronic Diseases), by presenting at scientific meetings (e.g., American Heart Association, Council on Cardiovascular Epidemiology, American Public Health Association), and by compiling special reports and monographs available to the scientific community. HCHS/SOL publication guidelines have been written to foster the analysis and publication of data. The reports on morbidity and mortality from next of kin and physicians and medical records are to be used to determine the cause of death of the participants.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

Expiration date display exemption is not requested. Displaying the OMB expiration date is appropriate for this submission, and will be printed on the HCHS/SOL documents.

A.18. Exceptions to Certification for Paperwork Reduction Act Submission

The data encompassed by this study will fully comply with all guidelines of 5 CFR 1320.8(b)(3) and no exception is requested to certification for Paperwork Reduction Act Submission.

A.19. Certification for Paperwork Reduction Act Submissions

The Certification for Paperwork Reduction Act Submission is attached as appropriate (page 2 of OMB 83-I form).