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

Supporting Statement Part A

OMB# 0925-0584

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IRB Approvals
Albert Einstein University
Northwestern University
San Diego State University
University of Miami
University of North Carolina Chapel Hill

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Albert Einstein University
Northwestern University (English and Spanish forms are in the same file)
San Diego State University
University of Miami

Introduction

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, other 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. The baseline examination concluded on June 30, 2011. 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 were 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.

Target recruitment included four thousand (4,000) men and women, between the ages of 18 and 74 years, 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

Information collection for HCHS/SOL was originally approved by OMB in March, 2008 for data collection including participant recruitment, a baseline examination, phone collection of dietary information, annual follow-up (AFU) and health provider contacts. Revisions to that collection were approved by OMB for 3 years in March, 2009. The current OMB clearance expires March 31, 2012. The current HCHS/SOL contract period ends March 31, 2013, and contract renewal is anticipated. AFU will continue during a renewal period. This is a request for OMB approval to continue annual follow-up (AFU) of living participants, informant and health

care provider contacts. Additional years of collection of AFU data will increase the identification of morbidity and mortality events from March, 2012 onward.

The baseline examination took place over a 3-year period from March 2008 through June 2011 and is now completed. The longitudinal AFU was initiated in March, 2009 (1 year after completion of the first baseline examinations) and was scheduled to re-occur for the following three years for each participant on the anniversary of their examination. This is a request to continue the annual follow-up (AFU) in order to update morbidity and mortality as well as to contact health care providers for outcomes ascertainment and to complete the one-time follow-up dietary data collection via the Food Propensity Questionnaire (for the portion of the cohort recruited between April-June 2011). The Food Propensity Questionnaire is only administered during the first AFU contact. All of these collections were previously approved by OMB.

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." Attached is the NIH memo dated September 2, 2011 indicating the Privacy Act applies to this information collection. (Attachment 1)

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 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

Annual follow-up of cohort members is used to (1) maintain contact and update address information on cohort participants, (2) update tracing information on two or more contact persons. The additional contacts serve as a designated backup if the participant cannot be reached. 3) ascertain the participant's vital status, and (4) document medical events/hospitalization and life events since the baseline examination. The Food Propensity Questionnaire (FPQ), administered only during the first AFU, is used to estimate a population's distribution of usual food intake.

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 Latino, 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.

A one-time extensive examination of this population sample and AFU have been completed under previous the previous OMB approval. The study 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. Study recruitment and sampling and sampling methodology have been documented in recent publications, 20 presentations and posters based on preliminary results have been presented at scientific conferences. Now that baseline data collection has been completed, numerous manuscripts are proposed and publications are forthcoming based on analysis of the complete data set. Additionally, the HCHS/SOL serves as the foundation for the following nine independent, investigator-initiated, grant-supported ancillary studies:

- Housing as an Obesity Moderating Environment (HOME) Study
- CALiCo – Genetic Epidemiology of Causal Variants Across the Life Course
- ECHO-SOL- Echocardiographic Hypertensive Heart Disease in Hispanic Subgroups
- Socioeconomic Position, Cultural Factors, and Psychosocial Risk and Resilient Factors in Relation to Metabolic Syndrome and DVD Prevalence in the Hispanic Community Health Study/Study of Latinos
- SOLNAS – Study of Latinos – Nutrition & Physical Activity Assessment
- Vision – Ocular Healthcare Utilization and Ocular Risk in Hispanics
- SOL Youth – Family, Individual & Environmental Influence on Hispanic Youth's CV Health Behaviors and Cardio-metabolic Profiles
- Sleep habits as a risk factor disease in HCHS-SOL – Sueno Sleep Ancillary Study
- GUARDIAN – Genetic and Epidemiologic Predictors of Glucose Homeostasis in Hispanics

The data collection instruments were administered in English and Spanish.

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

During the baseline examination, data were collected in the form of detailed interviews and an examination of study participants including fasting blood tests, a 2 hour glucose tolerance test, electrocardiogram, ankle-brachial pressure measurements, a dental exam, hearing tests, pulmonary function tests, sleep study, neurocognitive tests, and questionnaires to capture health behaviors and risk factors for many chronic diseases.

Annual follow-up continues to be conducted on individuals who participated in the baseline examination. Continued follow-up of the cohort is essential to provide morbidity and mortality updates for longitudinal follow-up. Study participants are contacted annually by phone as closely as possible to their baseline examination anniversary date and will continue to be contacted each year thereafter throughout the study. Physician and other health care providers are contacted for outcomes ascertainment, documentation of medical events/hospitalizations and life events since the baseline examination The FPQ is administered only during the first AFU phone call (one year from baseline examination) to provide a more complete picture of food consumption within the population. A timeline for AFU is attached. (Attachment 2)

The cross-sectional hypotheses for this study can be grouped into broad research areas. Below is a 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 Analysis

The longitudinal portion of this study was previously approved by OMB. It includes the annual follow-up for which a continuation is requested. The purpose of the AFU 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. Diagnoses are validated by obtaining and reviewing medical tests and other information in the medical record to determine whether the reported diagnoses meet fixed criteria for disease classification. A panel of physicians reviews this medical information to make the final determination for event outcomes of interest. 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 3½ years.

The AFU enables the ascertainment of the study outcomes as newly developed, incident events occur. 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 represent the measurements and scientific inquiries that could lead 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 uses 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 assessment 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 Multi-Ethnic 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. HHANES was a cross-sectional study without a longitudinal component and the MESA Study has approximately 1,500 Hispanic participants. 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

Participants are contacted annually after the baseline examination 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 in 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 August 9, 2011 Volume 76, Number 153, wherein public and affected agencies' comments were solicited is included. Two public comments were received. One comment questioned why government resources are being devoted to studying the health of Hispanic groups. The comment was acknowledged by NHLBI. The second comment, from an advocacy group, inquired about exploring the availability of paid sick leave and its relationship to Hispanic health. NHLBI acknowledged and followed-up on this comment.

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. (Attachment 3).

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

A second Working Group, Future Research Opportunities in the Hispanic Community Health

Study-Study of Latinos (HCHS-SOL), met on August 11, 2010 to discuss plans for a renewal.

The Working Group provided recommendations for future examinations and data collection. (Attachment 4).

Chair of the working group

Ileana Piña, MD, PhD, Case Western Reserve University, Cleveland, OH

Members
Ana L. Abraído-Lanza, PhD, Columbia University, New York, NY

Alain Bertoni, MD, PhD, Wake Forest University, Winston-Salem, NC

Gerard Criner, MD, Temple University, Philadelphia, PA

Michael Felker, MD, Duke University, Durham, NC

José Florez, MD, PhD, Broad Institute – The Broad Institute, Harvard Medical School, Boston, MA

Willa Hsueh, MD, The Methodist Hospital Research Institute, Houston, TX

Visheh K. Kapur, MD, MPH, University of Washington, Seattle, WA

Amit Khera, MD, MSc, University of Texas Southwestern Medical Center, Dallas, TX

Barbara Klein, MD, MPH, University of Wisconsin, Madison, WI

Marian McDonald, DrPH, MPH, MA, Centers for Disease Control and Prevention, Atlanta, GA

Kathleen Page, MD, MPH, Johns Hopkins University School of Medicine, Baltimore, MD

Julio A. Panza, MD. Georgetown University, Washington, DC

José Ordovas, PhD, Tufts University, Boston, MA

David Williams, PhD, Harvard School of Public Health, 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) (Attachment 5)

The HCHS/SOL Observational Study Monitoring Board (OSMB) met on June 22, 2007, and annually thereafter 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. At the November 19, 2010 OSMB meeting the Board congratulated the investigators on the study's success particularly in the areas of

recruitment and scientific productivity. Minutes from the November, 2010 OSMB meetings are attached (Attachment 6). The Board members are:

Odilia Bermúdez, Ph.D. 617-556-3183
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Gustavo Cruz, D.D.S. 202-690-5400
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Judy Dubno, Ph.D. 843-792-7736
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George Howard, Ph.D. (Chair) 205-934-4905
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Martha Medrano, M.D. 210-233-7016
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On May 10, 2011, the NHLBI Board of Extramural Advisors endorsed continuation of the study. On June 15, 2011, the NHLBI Advisory Council recommended the renewal of the contract to the Acting NHLBI Director. The NHLBI anticipates funding and is planning the renewal phase.

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

There are no clinic visits during the annual follow-up. There are no payments or gifts to respondents associated with the follow-up components of the study.

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 signed by participants prior to the baseline examination described the study to the participants, informed them of the risks and benefits of procedures and where to obtain information about the rights of research subjects. The consent forms were reviewed and approved by OMB in the prior submission. Additionally the HCHS/SOL Observational Study Monitoring Board annually reviews any issues involving human subject 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..

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 University of North Carolina at Chapel Hill Information Technology Services (UNC-ITS) Department for 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 on the secure file servers at UNC-ITS. or, 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-identified 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 was granted 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. HCHS Privacy Policy is attached (Attachment 7).

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 (https://biolincc.nhlbi.nih.gov/home/) 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

The questionnaires included in this renewal were previously approved. They include questions about health status, medications, hospitalizations, and cause of death. There are no new questions associated with the Food Propensity Questionnaire, annual follow-up call, informant contact or physician/health provider contact questionnaires.

Although providing the Social Security Number (SSN) was not required for participation, voluntary disclosure of this information was asked from participants at the baseline visit 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 were assured that declining to provide this information will not alter in any way their ability to participate in the project. At induction into the cohort, the HCHS/SOL Study requested disclosure of the participant's SSN, after presenting the participant with a statement that this disclosure was voluntary and failure to disclose the SSN would not affect his/her rights, participation in the study, nor the individuals' relation to the study. Field Centers may use personal identifying information to trace study participants who are lost to follow-up and search for deaths of cohort members through the National Death Index (e.g. SSN). No private companies are used to trace participants lost to follow-up through these means. SSN may also be used by authorized study personnel to verify the identity of decedents among the study participants who have the same first and last names as other members of the cohort, and may have changed their address.

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

The estimates for interview burden are based on experience in this study over the past three years.

Table A.12.1
ESTIMATE OF RESPONDENT BURDEN
HCHS/SOL

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response	Annual Hour Burden
Participant Telephone Interviews				
a. Follow-Up Call, Year 1	1,333	1	0.75	1,000
b. Follow-Up Call, Year 2	5,333	1	0.25	1,333
c. Follow-Up Call, Year 3	3,111	1	0.25	777.75
c. Follow-Up Call, Year 4,	3,111	1	0.25	777.75
c. Follow-Up Call, Year 5	2,075	1	0.25	518.75
c. Follow-Up Call, Year 6	1,037	1	0.25	259.25
			Subtotal	4,667
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
			Subtotal	642
			Grand total	5,309

Table A.12.2
Annualized Cost to Respondents

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Respondent	Hourly Wage Rate	Respondent Cost
Participants	16,000	1	0.2917	15.00	$70,008
Physician/hospital/ nursing home contact	1,254	1	0.50	55.00	$34,485
Informant Contact	30	1	0.50	15.00	$225
					Total $ 104,718

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 $104,718.

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. (8).This funding is committed by the budget office of the NHLBI, and extends for a six and one-half year period. This funding provided 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, the study has undergone a rigorous scientific review as described in Section 8.1

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

Program Change-- With this modification that covers continued annual follow-up of participants, the overall burden hours requested have been reduced to a total of 5,309 hours.

The overall burden for the remaining years of AFU has been reduced since the previous submission. The average time across the first three years for a participant with the AFU questionnaire was 30 minutes contact time per year. The goal for the fourth, fifth, and sixth years of follow-up was to reduce this contact time further to an average burden of 15 minutes for these later years.

Summary of changes to this submission:

Questionnaires added:

Annual Follow-up Qx Years 4, 5, 6: the fourth and fifth year contacts will have an interview format identical to the reduced content of the third year (15 minutes)

Questionnaires revised:

Annual Follow-Up Qx Year 3: modified to drop neurocognitive function resulting in a shorter administrative time. (15 minutes)

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

	Time elapsed after OMB approval	
Activity	**Start**	**Finish**
Annual Dietary Data Collection (FPQ)	0	6 months
Annual Follow-Calls	0	36 months
Outcomes Ascertainment	0	36 months
Primary Data Analysis	0	36 months
Publication and Secondary Additional Analysis	0	36+ 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 Diabetes Association,

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.