1The Hispanic Community Health Study/ Study of Latinos (HCHS/SOL)

Supporting Statement Part A

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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) was initiated in 2006 to: (1) study the prevalence of cardiovascular and pulmonary disease and other chronic diseases, and their risk and protective factors, (2) understand their relationship to all-cause, cardiovascular and pulmonary morbidity and mortality, and (3) understand the role of sociocultural factors (including acculturation) on the prevalence or onset of disease among over 16,400 Hispanics/Latinos of diverse origins, aged 18-74 years at enrollment, living in four U.S. communities: San Diego, California; Chicago, Illinois; Miami, Florida, and the Bronx, New York. In order to achieve these objectives, the HCHS/SOL had two integrated components:

1. Examination of the cohort following a standardized protocol, which consisted of interviews and clinical measurements to assess physiological and biochemical measurements including DNA/RNA extraction for ancillary genetic research studies.
2. Follow-up of the cohort, which consists of an annual telephone interview to assess vital status, changes in health status and medication intake, and new cardiovascular and pulmonary events (including fatal and non-fatal myocardial infarction and heart failure; fatal and non-fatal stroke; and exacerbation of asthma and chronic obstructive pulmonary disease).

The recruitment of participants was based on a multi-stage random sampling of the local community. Recruitment and examination of eligible individuals took place in three waves from March 2008 to June 2011. During each wave, similar census tracts were sampled, therefore yielding very similar groups of participants that represented the local community. The prevalence of the variables of interest has been compared, to the extent possible, among individuals who identified their ancestry with specific Hispanic groups of origin: Mexicans, Puerto Ricans, Cubans, Dominicans, Central Americans and South Americans. The findings of the baseline examination of the HCHS/SOL have demonstrated that the prevalence of cardiovascular risk factors is widespread across Hispanic groups and varies according to age, gender and Hispanic group of origin. Analyses and publications of baseline findings are underway. The longitudinal follow-up was initiated in 2009. To this date, participants have been followed for an average of 4 years.

In the proposed continuation of the study, in addition to the original objectives mentioned above, the HCHS/SOL also aims to: (1) understand the relationship between changes in risk or protective factor profile and the onset or progression of cardiovascular and pulmonary disease; (2) understand the relationship between changes in cardiometabolic risk profile and cardiac structure and function; (3) understand the relationship between changes in sociocultural factors (including acculturation) and changes in health; and (4) understand the relationship between baseline cardiovascular risk profile of women of childbearing age and the incidence of select pregnancy-related complications, and in turn, future incidence of cardiovascular disease. Some activities to be performed during the next six years of the HCHS/SOL will continue to be similar

to those in the previous six and a half year period, and others will be added:

(1) Perform a second examination of the cohort, which will include interviews and clinical measurements, to reassess select sociodemographic, sociocultural, socioeconomic, lifestyle and cardiometabolic variables evaluated at baseline.

   a. In order to assess the relationship between baseline and current cardiometabolic profile and cardiac structure and function, an echocardiogram (new non-invasive procedure) will be performed during this second examination.

   b. Comprehensive reproductive history of women of childbearing age, including history of pre-eclampsia, eclampsia and gestational diabetes mellitus between the baseline and second examination, will also be assessed during this second examination.

(2) Continue annual follow-up of the HCHS/SOL cohort to document the occurrence of cardiovascular and pulmonary endpoints (mentioned above).

   a. In addition to the ascertainment of the three primary endpoints, the incidence of pre-eclampsia, eclampsia and gestational diabetes mellitus after the second examination will be assessed.

Coordination of the research activities will continue to be performed by the HCHS/SOL Coordinating Center located at the University of North Carolina at Chapel Hill. The University of Illinois at Chicago will house the Chicago Field Center (previously at Northwestern University), while the other Field Centers will remain unchanged. An Echocardiography Reading Center housed at Brigham and Women's Hospital will lead the echocardiogram data collection, quality control, transmission and interpretation, and training of technicians for this component of the study. The duration of the new study period is six years.

This second phase of the study will consist of a much shorter examination than baseline. The research questions and scope of work are more targeted towards the reassessment of cardiovascular risk factors, reassessment of select sociodemographic and sociocultural factors, and the assessment of two new cardiovascular-related components [Appendix 3]. Therefore, the duration of this second visit is expected to be approximately 3 ½ hours (versus 6 hours at baseline). Investigators may capitalize on the established study infrastructure to propose and incorporate ancillary studies funded by other, non-contract mechanisms.

The endpoints ascertainment will include the adjudication of pregnancy-related complications between Visit 1 and Visit 2, and thereafter. Therefore, Visit 2 will include questionnaires that will address female reproductive history and pregnancy, and continuation of AFU initiated during the first funding period. One third of the cohort is still completing AFU 3, one third is completing AFU 4, and the other third has started AFU 5. Thus, in addition to continuing these three AFU interviews (during the funding period, but before Visit 2), AFU 6-11 interviews will take place as per the timeline [Appendix 3]. AFU 6-11 interviews will include

questions about pregnancies that occur after Visit 2 and health insurance status [Appendix 15, AFU 6-11]. AFU 6 interview will be shorter than the rest of the interviews, since it will take place close to the attendance to Visit 2, and replication of questionnaires would be avoided. Data abstraction from labor/delivery and other obstetrical or pediatric records will be added to the current medical acquisition procedures for the three original endpoints. Medical review of the diagnostic criteria and adjudication of pregnancy-related events of interest will be added to the ongoing endpoints ascertainment activities.

A participant disability questionnaire is also included in Visit 2. This questionnaire will be useful in assessing participants' disabilities prior to the visit and help the Field Centers prepare for and accommodate that need. In addition, the information collected via this questionnaire will be used in the socioeconomic and employment analyses, and will fulfill the requirement specified in Section 4302 of the Affordable Care Act.

In addition, the Pregnancy Complications History Questionnaire (PCE/PCS) and the Tobacco Use Questionnaire (TBE/TBS) were modified based on recommendations provided by Legacy during the 60-Day Federal Register period [Public Comments]. Amendments and additions of some questions regarding the frequency of use of certain tobacco products (TBE/TBS Items #3, 13, 13.a., 13.a.1, 14, 14.a., 14.a.1, 15, 15.a, 15.a.1, 16, 16.a., 16.a.1, and 19) and smoking habits during pregnancy (PCE/PCS Items 1g and 1h) were incorporated.

Justification

A.1 Circumstances Making the Collection of Information Necessary

The Hispanic/Latino population is the largest U.S. minority group. It increased by 43 percent between years 2000 and 2010, accounting for more than half of the growth in the total U.S. population during that period of time, and it is expected to experience a three-fold growth by 2050. Immigrant Hispanics/Latinos are influenced by factors less commonly found in established U.S. population groups but also experienced by other immigrant groups, including changes in diet, physical activity, and social network. Also, Hispanics have consistently had the lowest percent of people with health insurance in the U.S. for decades. Although often seen as one homogeneous demographic group, Hispanics 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. Diverse reasons for migration and migration patterns, the range of socioeconomic factors, and sociocultural and genetic backgrounds present among Hispanics are therefore expected to have varied influences on health maintenance and disease risk.

National data show that U.S. Hispanic/Latino populations overall have lower coronary heart disease (CHD) mortality rates than non-Hispanics/Latinos, but have an increased prevalence of obesity and diabetes. In addition, the Centers for Disease Control and Prevention's National Center for Health Statistics reported in 2011 that Hispanics, especially Hispanic women, had a higher life expectancy any other racial/ethnic group. These findings raise questions regarding the role that unknown or unmeasured protective factors may be exerting despite the presence of well-known adverse health factors among Hispanics living in the U.S. Observational data are needed to determine which changes associated with immigration and acculturation to living in the U.S. are related to protection from or increased risk of disease among Hispanics, and to determine how best to prevent the changes in risk factors that are most harmful to health. Research in 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, is actually lower in Hispanics/Latinos than in non-Hispanics, or the risk of other diseases, such as asthma, obesity or diabetes, is higher in some Hispanic groups, identification of factors contributing to these differences will be relevant to both Hispanics and non-Hispanics.

The Hispanic Community Health Study/Study of Latinos (HCHS/SOL) study design and sampling design were described in our original application submitted in 2008, and have been published in the journal Annals of Epidemiology [Sorlie et al and LaVange et al, Appendix 1]. Following a multi-stage, random sampling of the local communities, over 16,400 individuals who self-identified as Hispanic/Latino were enrolled. The breakdown of Hispanic groups

represented in the cohort is 39% Mexican, 16% Puerto Rican, 14% Cuban, 9% Dominican, 6% Central American (mostly Nicaraguans, Guatemalans and Hondurans), 3% South American (mostly Peruvian, Colombian and Ecuadoran), and 3% Hispanics who self-identified with more than one group [Daviglus et al, Appendix 1]. While most prior research on Hispanics in the U.S. has concentrated on those of Mexican origin, each Hispanic group has differing place of birth (including U.S.-born), cultural and behavioral traditions, food and nutrition practices, reasons for immigration and, from the little information currently available, health and risk of disease. Thus, research on one group will have not provided answers related to the other groups. The *baseline examination* consisted of a very comprehensive data collection, utilizing questionnaires and measurements of risk factors and select diseases that included clinical measures and biospecimen collection (serum, plasma, whole blood, urine and DNA/RNA). The data collected and measurements performed at baseline are under active analysis and publication, considering several analytical approaches, as applicable to the specific research question. For example, the study sample supports the cross-sectional analysis of the prevalence and distribution of baseline risk factors and diagnosed diseases among different age, gender and Hispanic groups, and/or Field Center. In addition, the study sample size supports evaluation of the relationships between the various risk factors, demographic factors, cultural factors, and prevalent diseases identified at baseline.

Upon completion of the baseline examination, *the longitudinal component* of the study was initiated. The relationship between cardiovascular risk or protective profile and cardiovascular events, for example, would only be understood through a longitudinal observational phase and systematic ascertainment of select endpoints. Before the inception of the HCHS/SOL, knowledge about cardiovascular mortality and its risk factors among Hispanics in the U.S. was based on studies of Mexican or Mexican American communities or national death data. The HCHS/SOL, as a longitudinal cohort study in Hispanic/Latino health, meets the need about understanding the development of risk factors and disease among diverse Hispanic populations. However, the number of cardiovascular incidents that happened during the planned follow-up period (average of three-and-a-half years) of the first study phase was too small (less than 100) for appropriately powered correlation analyses, but is consistent with lower rates of cardiovascular disease reported for Hispanics than is seen in the general population.

Therefore, in 2011, the National Heart, Lung, and Blood Institute (NHLBI) approved the renewal the funding of the HCHS/SOL. This new study phase will have three main components: continuation of the longitudinal follow-up, re-assessment of select cardiovascular variables evaluated at baseline, and the assessment of new variables.

The *continuation of the longitudinal phase* of this unique cohort of Hispanic individuals will allow for a better powered analysis of the relationship between baseline general health and cardiovascular profile and incident events, specifically all-cause mortality, and fatal and non-fatal heart, stroke and pulmonary events. At baseline, approximately 53% of individuals aged 18-64 years had health insurance, whereas approximately 83% of those 65 years or older did. The continuation of the longitudinal phase will provide the opportunity for more detailed and complex analysis of other cohort characteristics, for example, the relationship between health insurance status and access to health care and select health endpoints.

The re-assessment of select variables studied at baseline will provide the opportunity to understand differences in patterns of onset of disease among the different Hispanic groups and the mediators of these differences. Due to their heterogeneity, studying the influence of diverse metabolic, genetic, socioeconomic and sociocultural determinants of health on the onset of select diseases among Hispanics will provide a foundation for understanding mechanisms of disease and more targeted preventive strategies for these populations. The variables that will be reassessed include blood pressure, anthropometric measurements, oral glucose tolerance test, hemoglobin A1c, lipids and lipoprotein profile, renal and hepatic function, sociodemographic descriptors, occupational history, sociocultural descriptors, health insurance status and utilization of health care services. Whole blood, serum, plasma and urine biospecimens will also be stored for future analyses.

In addition to the re-assessment of the selected variables mentioned above, two new components will be assessed during the second visit: cardiac function and structure (via echocardiography); and detailed reproductive history in women of childbearing age, including identification of history of pre-eclampsia, eclampsia and gestational diabetes mellitus between the baseline visit and Visit 2. The burden of obesity and diabetes in the Hispanic population, and specifically in this cohort, makes the heart a target organ not only for atherosclerosis but also for dysfunctional contractility and remodeling, which may eventually lead to heart failure. Because the prevalence of diabetes, obesity and other cardiovascular risk factors varies across Hispanic groups and ages [Daviglus et al, Appendix 1], the study of the variability of the interaction of these and other factors on cardiac remodeling would be a great contribution to the understanding of the pathophysiology of heart failure both among Hispanics and the general population. At the same time, the role of pre-eclampsia, eclampsia and gestational diabetes mellitus on the long-term of women's cardiovascular health is not completely known. It is not clearly understood whether these pregnancy-related complications are the consequence of predisposing factors or the triggering factors for future cardiovascular disease. In the cohort, there are approximately 3,800 women who were of childbearing age at enrollment. Thus, the cohort offers a unique opportunity to retrospectively and prospectively evaluate the relationship between baseline cardiometabolic risk profile and the incidence of pre-eclampsia, eclampsia and gestational diabetes mellitus between baseline and Visit 2, and thereafter.

The study of cardiovascular and pulmonary disease, and other chronic diseases, in the HCHS/SOL has become enriched by the incorporation of genome-wide association studies and genetic analyses. These are currently performed under a separately approved and contract-funded NHLBI initiative, Omics in Latinos (OLa). While the first genetic analyses will be based on the phenotypes described at baseline, the assessment of change in the selected variables and the ascertainment of a higher number of cardiovascular and pulmonary events during the follow-up will provide a unique opportunity to perform genetic analyses in relation to risk or protective profile.

The study objectives are clearly within the NHLBI mandate, and the Institute has the unique capability to coordinate this complex study within four different communities and over an extended period of time. The NHLBI mandate is described in the PHS Act, Section 421 (42 USC 285b-3) [Appendix 2] and specifies 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."

A.2. Purpose and Use of the Information Collection

The overall purpose of the continuation of the HCHS/SOL is to estimate the incidence of cardiovascular risk factors and risk factors for other chronic diseases, and their relationship to baseline cardiometabolic and general health profile and to the incidence of cardiovascular events (morbidity), cardiovascular mortality and all-cause mortality in a randomly selected sample of men and women who self-identified as Hispanic, and who represent four different communities in the U.S. The Field Centers are located in San Diego (San Diego State University), Chicago (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. In addition, an Echocardiography Reading Center at Brigham and Women's Hospital will oversee the collection of echocardiographic data and its interpretation and analysis.

The overall objectives will be accomplished through the continuation of the follow-up and re-examination (Visit 2) of the cohorts recruited in each of these communities. The current contract period is 6 years with cohort re-examination scheduled to occur over a three-year period [Appendix 3]. Visit 2 data will be collected in the form of interviews and clinical measures, as described in pages 11 and 12. Annual follow-up (AFU) of the cohort will continue throughout the duration of the contract (6 years).

The longitudinal data collection of this study has two components. The first component 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, abstract relevant information and produce a validated diagnosis for the disease, which will become part of the study database. This process will provide identification of incident occurrences of coronary heart disease, stroke, heart failure, exacerbations of chronic obstructive lung disease and asthma, and pregnancy-related complications (pre-eclampsia, eclampsia and gestational diabetes mellitus). In the time frame of this study period (6 years) the expected average follow-up for incident disease will be 5 ½ years. This means that by the end of the follow-up period in the current contract, one third of the cohort would have been followed for 10 years, another third for 9 years, and the other third for 8 years since the baseline exam. 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, which should bring the total number of incident myocardial infarctions or coronary heart disease deaths to approximately 266 since follow-up began. The total number of deaths from all causes is projected to be 539.

Analysis of Visit 2 and follow-up data and preparation of the corresponding manuscripts will take place during this study period. NHLBI will use the results to describe changes in biological risk and protective factors, social determinants of health and sociocultural factors over time, and their relationship to genetics, onset of disease and fatal and non-fatal disease events in Hispanic/Latino populations.

A re-examination and continuation of the AFU of this population sample of U.S. Hispanics is scientifically important and has public health and policy implications. The characterization of this heterogeneous minority group (and its different national origins) will fill gaps in current knowledge of the relationship between social determinants of health, sociocultural factors, risk factor profile, metabolic phenotypes and genotypes and objectively measured disease parameters, and will be uniquely informative to health policy and clinical guidelines experts. Since information on these attributes is fragmentary among Hispanics, the re-examination designed for this contract period is a 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, be presented as policy recommendations by the NHLBI through public education and health promotion and disease prevention programs. Recommendations for the future continuation of the study and a possible repeat examination of the cohort will also be pursued.

A.3. Use of Information Technology and Burden Reduction

The Privacy Impact Assessment was performed, and was determined to apply. 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 interviewer 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, validated by the system (e.g. out of range or invalid values, impossible dates or times). The values failing the quality checks cause an error message to be displayed that 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 checking the data, the system permits users to enter text into 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 provide 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 diverse 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 Hispanic groups, assessment of cardiovascular and pulmonary causes of death, retrospective and prospective incidence of pre-eclampsia, eclampsia and gestational diabetes mellitus, and socioeconomic and sociocultural assessment; thus, it does not duplicate previous or ongoing research in this population.

Epidemiological studies that have included Hispanics/Latinos in their populations include the current National Health and Examination Survey (NHANES), the Hispanic Health and Nutrition Examination Survey (HHANES), the Multi-Ethnic Study of Atherosclerosis (MESA), the San Antonio Heart Study, the San Luis Valley Diabetes Study, the Corpus Christi Heart Project, the Boston Puerto Rican Health Study and the Northern Manhattan Study (NOMAS). NHANES consists of a cross-sectional analysis of a diversity of health aspects and examinations, and does not include a longitudinal component. The HHANES was a one-time cross-sectional study of a sample of Mexicans from California, Arizona, New Mexico, Colorado and Texas, Puerto Ricans from New York, New Jersey and Connecticut, and Cubans from Dade County, Florida performed in the early 1980s. The MESA includes approximately 1,600 individuals of

diverse Hispanic ancestry, a small sample size to ascertain differences in incidence of cardiovascular events among different Hispanic groups. The San Antonio Heart Study, the Corpus Christi Heart Project and the San Luis Valley Diabetes Study have focused on Hispanics of Mexican ancestry in Texas and Colorado, and on specific health/disease measures. The Boston Puerto Rican Health Study focuses on Puerto Ricans residents of the Boston area, and primarily evaluates the relationship between stress and diet and their effect on cardiovascular disease. The NOMAS is designed to investigate differences in stroke risk profile among non-Hispanic whites, blacks and Hispanics (the majority are Dominican) residents in Washington Heights, New York City. Given their cultural, migration history and patterns, time of immigration in the U.S., years living in the U.S., 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. Thus, the unique features of HCHS/SOL do not exist in any other study.

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, pregnancy-related complications 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 during Visit 2 and at AFU phone calls. Participants will be contacted annually for six 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 seven times throughout the duration of the study. HCHS/SOL cohort retention practices thus far have demonstrated that annual contacts are absolutely necessary to maintain records of personal contact information and participants interested in the study. Although most of the participants still live in the same census tracts or close to their original neighborhood, moving and changing telephone numbers are frequently reported. Home visits have been necessary and a very effective way to learn the participant's vital status and health information. If data are collected less frequently, relevant information about cause and circumstances of death, changes of health status, changes in health insurance 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

definitely be missed. This would negatively impact the main research questions of the longitudinal component.

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

The 60 day FRN was published on March 25, 2014 (Vol. 79, No. 57, pages 16345-16347). Three comments were received; they are attached in the document entitled "Public Comments." Based on recommendations received from the organization Legacy during this period, the Pregnancy Complications History Questionnaire (PCE/PCS) and the Tobacco Use Questionnaire (TBE/TBS) were modified. Amendments and additions of some questions regarding the frequency of use of certain tobacco products (TBE/TBS Items #3, 13, 13.a., 13.a.1, 14, 14.a., 14.a.1, 15, 15.a, 15.a.1, 16, 16.a., 16.a.1, and 19) and smoking habits during pregnancy (PCE/PCS Items 1g and 1h) were incorporated.

The HCHS/SOL initiative was developed by the Division of Cardiovascular Sciences (previously known as 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"[Appendix 4]. A second working group, "Future Research Opportunities in the Hispanic Community Health Study- Study of Latinos (HCHS/SOL)" [Appendix 5] was convened on August 11, 2010, to discuss the potential research opportunities to be explored in a continuation of the study. This working group recommended the continuation of the longitudinal component of the study, the reassessment of select variables evaluated at baseline, the expansion of the evaluation of sociocultural factors, and the incorporation of specific new research questions, including the evaluation of cardiac structure and function and the study of pregnancy-related complications and cardiovascular disease in women.

A.8.1 Scientific Review

The scientific merit of the initiation and renewal of the study was reviewed at many steps including the final review by the NHLBI Advisory Council on June 11, 2011. The NHLBI Advisory Council advises the Secretary of DHHS, the Assistant Secretary for Health, the Director of National Institutes of Health, and the Director of the National Heart, Lung, and Blood Institute on matters relating to the cause, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases; the use of blood and blood products and the management of

blood resources; and on sleep disorders. The Council may also make recommendations to the Director, NHLBI, respecting research conducted at the Institute. The Council meets four times a year--winter, spring, and two meetings in the fall. A copy of the relevant minutes from this meeting and a roster of the June 11, 2011 Council members are included [Appendices 6 and 7].

On July 11, 2012, competitive Requests for Proposals (RFP) for the four Field Centers, a Coordinating Center and an Echocardiography Reading Center were issued. The Center for Scientific Review convened a special external review panel to perform the primary scientific review the applications on January 15, 2013. On February 8, 2013, the NHLBI Division of Cardiovascular Sciences and the NHLBI Contracts Office performed an internal secondary review of the applications. Comments and questions shared by both the primary and secondary reviewers were discussed with each of the Offerors, who submitted responses and revisions to the applications, accordingly.

The HCHS/SOL Observational Study Monitoring Board (OSMB) has met annually during the course of the study to advise the NHLBI, monitor study progress and performance, and consider issues related to participant safety and privacy. At the November 8, 2013, meeting the OSMB reviewed and approved the HCHS/SOL informed consent, examination protocol and interview questionnaires for the second visit, and unanimously and enthusiastically supported continuation of the study. Minutes from the OSMB meetings, along with the OSMB roster are included [Appendix 8].

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

Participants will not be paid for their participation. During the proposed period, they will receive a lump sum compensation in the amount of $75 to cover expenses associated with participating in the examination including childcare and transportation (gas, tolls, parking, public transit), and mobile phone/phone card charges associated to the annual phone calls. This total compensation will be made available to the HCHS/SOL participants only (not to friends, proxies, relatives or family members).

In addition, we found some publications on the topic of payment or compensation to research subjects, and none points towards specific recommended amounts or scale [Appendix 9]. The perspective of bioethicists is that the value of the amount is interpreted by the subject, and that compensation for transportation and childcare is not perceived as coercive, but well justified.

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5. Singer E, Couper MP: Do incentives exert undue influence on survey participation? Experimental evidence. J Empir Res Hum Res Ethics 2008; 3: 49-56

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. Research involving human subjects shall not be conducted under this contract until the protocol has been approved by National Heart, Lung, and Blood Institute, written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self-designated form, **provided** that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310). As each of the Field Centers, the Echocardiography Reading Center, 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 [Appendix 10].

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 Board reviews 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 [Appendix 11]. Additionally, the HCHS/SOL OSMB 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 are 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 are not disclosed and data are reported only in aggregate.

A.10.3 Privacy Act

Information obtained from the study is 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 [Appendix 12].

Individuals are 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 are only 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 limited access data release with only the information pertinent to the approved analyses is prepared with no personal identifiers included (as described in Section A.10.6). Each recipient of limited access data must complete a data use agreement affirming that they will comply with all NIH policies. 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 centralized data management system (DMS) is the initial level of security. Each DMS user has a unique user ID with access levels and permission controlled by a local security administrator for the study. Field center staff are locally trained and certified in security and confidentiality procedures in collecting and handling health research data. All data collected at the field centers and in hospital record rooms are encrypted by the data management 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 is required to complete a confidentiality certification procedure upon employment. All Coordinating Center staff is instructed in procedures for maintaining data confidentiality and sign a form indicating their awareness of the necessity of maintaining confidentiality of data [Appendix 13]. Staff is informed that any inappropriate use or disclosure of confidential data will be cause for immediate termination of employment at the Coordinating Center.

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 has obtained 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.) will be reported to outside public health agencies or other explicitly authorized authorities. The study, with permission of the participants, uses

identifying data to link to the National Death Index and possibly other medical databases. In this process, the data are provided and linked using the data security provisions provided by these systems.

A.10.6. Coordinating Center Data Management and Computing

Data are retrieved from the study database and converted into SAS files on a regular schedule (e.g., monthly). Sensitive information is stored on a confidential section of the network file server and only trained staff with a proven need to have access (e.g. recruitment, endpoints records abstraction and classification) can access certain study files. 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 datasets and documentation that meet current guidelines [http://www.nhlbi.nih.gov/funding/setpreparation.htm] for distribution to outside investigators through the NHLBI data repository after closure checks are performed of the yearly Visit 2 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. Datasets 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 this policy. During the study funding period, limited access to the Visit 2 examination and outcomes data is granted only to the participating investigators at the Field Centers, the Coordinating Center and the Echocardiography Reading Center. Datasets and documentation are to be prepared during the study funding period, and released through the NHLBI data repository no later than 3 years after the end of the examination cycle, or two years after releasing it to the study investigators.

A.11. Justification for Sensitive Questions

Social Security Number is not required for participation, but voluntary disclosure of this information is asked of participants for 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. At the same time, excessive alcohol intake has been associated with cardiomyopathy, pharmacologic interaction with prescribed and over-the-counter medications, depressive symptoms and other health-related adverse effects.

Current medication use is being determined since blood chemistry values may be 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 is necessary to assess whether a participant has either of these conditions.

Citizenship/documentation status: Since the Affordable Care Act (ACA) is expected to be fully implemented at the beginning of 2014 the HCHS/SOL is uniquely positioned to evaluate the effects of changes in eligibility for health insurance coverage on health outcomes of Hispanics who previously were not eligible. At the same time, immigrants without the required documentation to live in the U.S., including some Hispanics, will not be eligible for health insurance under the ACA. Therefore, during the continuation of the study, we will ask questions about citizenship and visa status to HCHS/SOL participants. Comparing utilization of health care services and health outcomes between those who are insured and those who are not, and changes in health outcomes between those who have had health insurance for a long time versus those who are able to acquire it after the implementation of the ACA versus those who do not, for example, will be significant contributions to health policy experts and the study of social determinants of health of Hispanics and other immigrants to the U.S. Since these questions are considered very sensitive, the Field Centers' Advisory Community Boards were consulted on expected obstacles and how to best address them. Although there is agreement that these questions are of a highly sensitive nature, the Advisory Boards and other community representatives agreed that these are important questions. They recommended making these questions optional, and administering them at the end of the examination. These questions have been incorporated into the Health Utilization Questionnaire [Appendix 14]. Interviewers will be trained on addressing these questions in the most respectful manner and clearly explaining to participants that their responding is voluntary.

A.12. Estimates of Hour Burden

The estimates for procedure and interview burden [Tables A.12.1 and A.12.2] are based on the experience during the baseline examination, previous experience in prior studies using

similar protocols, and on staff volunteers pre-testing interview forms.

A.12.1 ESTIMATES OF HOUR BURDEN (APPENDICES 11, 14 AND 15)					
Type of Respondents	Survey Instrument	Number of Respondents	Number of Responses Per Respondent	Average Time per Response (in hours)	Total Burden Hours
Participants Visit 2 Examination (Appendices 11 and 14)	Pre-visit scheduling & safety screening (Appendix 14 -Procedures-ELE bilingual)	13878	1	2/60	463
	Reception, informed consent (Appendix 11), medical releases	13878	1	20/60	4626
	Ppt. disability screening	13878	1	4/60	925
	Ppt. safety update and routing (Appendix 14 -Procedures-PSE bilingual)	13878	1	2/60	463
	Change clothes, urine specimen (Appendix 14-Procedures-BIO)*	13878	1	10/60	2313
	Updated personal information	13878	1	5/60	1157
	Anthropometry	13878	1	7/60	1619
	Determination of fasting & blood draw (Appendix 14-Procedures-BIO)*	13878	1	11/60	2544
	Determination of blood glucose, OGTT (Appendix 14-Procedures-BIO)*	13878	1	6/60	1388
	Seated BP	13878	1	9/60	2082
	Echocardiography	8000	1	30/60	4000
	2-hour blood draw, snack (Appendix 14-Procedures-BIO)*	13878	1	12/60	2776
	Personal Medical History	13878	1	10/60	2313
	Reproductive Medical History	9000	1	9/60	1350
	Pregnancy Complications History	9000	1	6/60	900
	Socio-economic Status – Occupation	13878	1	3/60	694
	Health Care Access and Utilization	13878	1	15/60	3470
	Chronic Stress	13878	1	4/60	925
	Family Cohesion	13878	1	5/60	1157
	Social Support	13878	1	3/60	694
	Acculturation	13878	1	3/60	694
	Well Being	13878	1	4/60	925
	Abbreviated Medication Use	13878	1	4/60	925
	Tobacco Use	13878	1	7/60	1619
	Alcohol Use	13878	1	3/60	694
	Participant Feedback	13878	1	12/60	2776
	Total			206/60	**43492**
Participants AFU Phone Interview (Appendix 15)	AFU Year 3	3146	1	15/60	787
	AFU Year 4	9033	1	15/60	2258
	AFU Year 5	14259	1	15/60	3565
	AFU Year 6	16222	1	15/60	4055
	AFU Year 7	16222	1	15/60	4055
	AFU Year 8	16222	1	15/60	4055
	AFU Year 9	16222	1	15/60	4055
	AFU Year 10	16222	1	15/60	4055
	AFU Year 11	16222	1	15/60	4055
	Total			120/60	0
Physicians and/or other	Hospitalization records/ physician interview (Appendix 16, PQE)	1591	1	30/60	796

health care providers					
Informants	Informant Interview Deaths (Appendix 16, IIE/IIS)	154	1	30/60	77
	Total				**873**

*The BIO form covers change of clothes, fasting blood glucose determination, fasting blood and urine collection, first glucose determination, OGTT and 2h glucose draw, as broken down in this table. The sum of all activities is 39 min.

TABLE A.12.2
ESTIMATES OF ADMINISTRATION TIME BURDEN FOR EXAMINATION AND QUESTIONNAIRES
(APPENDICES 11 AND 14)

Exam Procedure, fasting status specification (F)	**Estimated time (minutes)**
Fasting block	**67**
Participant scheduling and safety screening	02
Reception, informed consent, change clothes, urine specimen	30
Participant disability screening	04
Participant safety update and exam routing	02
Updated Personal identifiers and contacts	05
Anthropometry (F)	07
Determination of fasting status, phlebotomy (F), Glucose load	17
Procedures, flexible sequence	**51**
Seated BP	09
Echocardiogram	30
2-hour post glucose load blood draw, snack	12
Blocks of interviews, flexible sequence	**76**
Alcohol Use	03
Socioeconomic background and occupation	03
Health care use	15
Personal Medical History	10
Medication use survey	04
Reproductive History and Pregnancy Complications	15
Sociocultural- chronic stress, family cohesion, acculturation, social support	15
Tobacco use	07
Well Being	04
Visit Termination	**12**
Change to street clothes and exit debriefing	10
Participant feedback questionnaire	02
Total Examination and other procedures time	**130**
Total Questionnaire interview time	**76**
Total Visit 2 participant time	**206**

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

The annualized cost to the participants consists of the cost of their time (Table A.13.1)

for which no remuneration is given. Assuming $10 per burden hour for participants and informants and $50 for physicians and other professional health care respondents, the estimated annual cost for time is $974,015. The estimated hourly wage was retrieved from the Bureau of Labor Statistics in the U.S. Department of Labor.

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.

TABLE A.13.1 ANNUALIZED COST TO RESPONDENTS

Form Name	Type of Respondent	Number of Respondents	Total Annual Burden Hours	Hourly Wage Rate	Total Annual Cost
Visit 2 Examination scheduling & consent	Participant	13878	463	$10.00	$305,455
		13878	4626		$46,260
Safety screening		13878	463		$4,630
Disability screening		13878	925		$9,250
Biospecimen collection		13878	2313		$23,130
Personal information		13878	1157		$11,570
Anthropometry		13878	1619		$16,190
Seated BP		13878	2082		$20,820
Personal Medical History		13878	2313		$23,130
Reproductive Med.Hist.		9000	1350		$13,500
Pregnancy Complications		9000	900		$9,000
Economic status		13878	694		$6,940
Health care access		13878	3470		$34,700
Chronic stress		13878	925		$9,250
Family cohesion		13878	1157		$11,570
Social Support		13878	694		$6,940
Acculturation		13878	694		$6,940
Well being		13878	463		$4,630
Abbrev. Medication Use		13878	925		$9,250
Tobacco use		13878	1619		$16,190
Alcohol use		13878	694		$6,940
Participant feedback		13878	2776		27,760
Annual Follow-up, AFU Year 3 Interview	Participant	3146	787	$10.00	$7,870
Year 4 Interview		9033	2258		$22,580

Year 5 Interview		14259	3565		$35,650
Year 6 Interview		16222	4055		$40,550
Year 7 Interview		16222	4055		$40,550
Year 8 Interview		16222	4055		$40,550
Year 9 Interview		16222	4055		$40,550
Year 10 Interview		16222	4055		$40,550
Year 11 Interview		16222	4055		$40,550
Hospitalization records/ physician interview	Physician/other health care providers	1591	796	$50.00	$39,800
Informant Interview Deaths (Appendix 16)	Informant	154	77	$10.00	$770
				Total	0

A.14. Annualized Cost to the Federal Government

The Hispanic Community Health Study/Study of Latinos is run by contractors with NHLBI staff also contributing to the study. The total average annualized cost to the U.S. Government for the information collection in the HCHS/SOL is $11,546,681 per year. Of this total, the annualized cost of monitoring the project by NHLBI personnel is estimated at $201,348. This is itemized in Table A14.1.

TABLE A.14.1 AVERAGE ANNUALIZED COST FOR MONITORING THE PROJECT

Personnel	GS Grade and Step	Annual Salary	% Time	Cost
Contracting Specialist	11-5	$71,504	50	$35,752
Contracting Officer	13-5	$101,914	20	$20,383
Program Analyst	13-5	$101,914	10	$10,191
Project Officer	14-10	$138,136	75	$103,602
Branch Chief	15-10	$157,100	20	$31,420
Total cost				$201,348

The annualized cost of the contracts is itemized in Table A.14.2. The annual budget currently approved for funding by NHLBI is attached [Appendix 17]. This funding is committed by the budget office of the NHLBI, and extends for a six-year period. This funding provides for the Visit 2 scheduling process, Visit 2 examination, and ascertainment of fatal and non-fatal events for cardiovascular and lung diseases for an average of 5 ½ years.

TABLE A.14.2 AVERAGE ANNUALIZED COST OF THE CONTRACTS TO THE FEDERAL GOVERNMENT

	Personnel	Equipment	Subcontracts	Other	Overhead	Total
HCHS/SOL Field Centers, Coordinating Center and Echocardiography Reading Center	$6,375,811.17	$20,260.83	$688,625.17	$1,012,679.33	$3,249,015.00	$11,345,333.33

A.15 Explanation of Program Changes and Adjustments

This is a revision of a currently approved information collection request for the second phase of the study, which will consist of a much shorter examination than baseline. Details of the specific changes are detailed in the in summary on page 1. The changes have resulted in a decrease in burden from 48,114 to 30,940.

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

The HCHS/SOL staff will collect most of the information after obtaining OMB approval. Ongoing AFU interviews are performed under OMB approval obtained in 2011, and expiring on December 31, 2014. The continuation of the AFU and the rest of the protocol will be performed after obtaining new OMB approval. The Coordinating Center, Field Centers and the Echocardiography Reading 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
Visit 2 data collection	1 month	36 months
Annual participant (or proxy) contact for AFU	Ongoing	60 months
Preliminary and final analyses	12 months	60 + months
Presentations at scientific meetings and submission of manuscripts to journals	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. *Journal of the American Medical Association, Circulation, Annals of*

Epidemiology), by presenting at scientific meetings (e.g., those convened by the American Heart Association and its Council on Cardiovascular Epidemiology, American Public Health Association, American Diabetes 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. In addition, study participants, their immediate communities, the Hispanic community at large and the general public have been and will be informed of study findings. Examples of printed materials for all these audiences have been included under Appendix 18.

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).