MINUTES
Observational Study Monitoring Board
for the Hispanic Community Health Study – Study of Latinos (HCHS-SOL)
Meeting, June 21-22, 2007

PARTICIPANTS:
OSMB Members Present: George Howard (Acting Chair), Odilia Bermudez, Esteban Burchard, Hannia Campos, Gustavo Cruz, Judy Dubno, Martha Medrano

OSMB Members Absent: Enrique Caballero, Anne Newman

Investigators: Martha Daviglus, Aida Giachello, Neil Schneiderman, Sylvia Smoller, Greg Talavera

Data Coordinating Center Staff: Gerardo Heiss (co-I), Lisa La Vange (co-I), Jeff Oberhaus

NHLBI Staff: Jean Olson, Executive Secretary; Larissa Aviles-Santa; Kristi Cooper; Lorraine Silsbee; Paul Sorlie
NIDCD Staff: Howard Hoffman

INTRODUCTION: Dr. Howard convened this first scheduled OSMB meeting at 6:35 p.m. Conflict of interest issues had been filed by all members, reviewed, and addressed as appropriate prior to the meeting. The Executive Secretary presented the proposed OSMB Charter (attached), including the Board's mission and responsibilities; operational points were discussed and requested modifications noted for incorporation into the document. The Project Officer gave an overview of study objectives, design, organization, and administrative structure.

STUDY DESCRIPTION: The HCHS-SOL is a multi-center longitudinal cohort study of Hispanics in the US initiated in October 2006 by NHLBI with co-support from 6 other NIH Institutes. The study objectives are to identify the prevalence of protective and harmful factors for diseases, disorders, and conditions in Hispanic populations and to determine the role of acculturation and other mediators in their prevalence and development.

STUDY STATUS: Substantial progress has been made in developing appropriate recruitment strategies and selecting components for the cohort exam, scheduled to begin in October 2007. The sampling plan for recruitment involves probability sampling imposed on those census tracts within the geographical areas of interest identified by each field center. Sample allocations are designed to allow baseline comparisons of cohort subgroups across regions of origin as well as analysis in the combined group for a broad spectrum of clinical outcomes occurring during the 3.5 years of follow-up. The initial contact of potential participants will be mailings to the selected households, followed by phone contacts to screen for eligibility or home visits for in-person screening for households not reachable by phone. Recruitment will be continually monitored to make mid-course adjustments to household selection probabilities in order to obtain the desired age distribution in the cohort.

Creating the informed consent template involved numerous considerations, particularly how to describe the collection and sharing of genetic material and information. The investigators are planning to prepare DVDs and brochures to give potential participants more information about genetic research before consenting, so participants can understand what this entails. Incentive payments are not approved contract costs and will not be offered, but a $75 reimbursement is authorized to cover costs of participation such as transportation and child care expenses.

All exam questionnaires will be available in both English and Spanish and will be administered by bilingual interviewers. Criteria for instrument selection included relevance to scientific goals, validity, repeatability, and prior use by other studies. Those questionnaires requiring translation will be reviewed for accuracy and tested by focus groups and volunteers representing all regions of origin of interest in the study. Completing all questionnaires is estimated to require approximately 3.5 hours.

The order of exam procedures will be planned to minimize participant waiting time. Blind replicate blood and urine samples will be collected on 5% of the cohort for quality control purposes; the total blood volume collected will not exceed 80 cc. Use of a glucometer is being considered to screen for diabetes before the oral glucose tolerance test is done. All participants will have spirometry, but only those with possible obstructive disease will receive bronchodilator (inhaled albuterol) and repeat spirometry. The Board noted that expected values for FEV_1 and FVC in Latinos are based on measurements in Mexicans, which may not be representative of Latinos from other regions of origin; this study is well positioned to set similar standards for these other groups. A dental exam is being done, but this does not explicitly include a screen for oral cancer. The estimated time required to complete all exam procedures is 2.75 hours.

All medically relevant exam results will be reported back to participants and, with their permission, to their health care providers. Alert values and accompanying advice for follow-up are compliant with current clinical guidelines. For data obtained during participant visits, the Coordinating Center will post web-based alert reports available to the field centers the next morning for feedback to participants; results of central lab assays and reading center interpretations will be provided when available. Participants requiring emergent follow-up during their visits will be escorted by clinic staff to the Emergency Room to help expedite evaluation and treatment. For non-emergent referrals, all sites are developing lists of health care resources for those with no health insurance. Field site staff will ensure that appropriate follow-up is obtained.

Staff central training sessions are planned for July and August. Where possible, staff will be trained and certified in several exam components to provide back-up as needed. In addition to staff training and certification, quality control efforts will include direct observations, audio taping of interviews, site visits, and quantitative assessment of data collected.

The policies and application process for ancillary studies were reviewed and are available on the study website. An ancillary study proposal already submitted (PI: Allison) proposing to obtain carotid ultrasound scans cohort subgroup was presented to the OSMB for consideration.

All field centers have established local community advisory committees to collaborate with the study on promoting community support, outreach and education. Strategies include establishing partnerships with community leaders, Hispanic and professional organizations; using trained community health promoters and participant navigators at clinic sites; and training staff on relevant cultural considerations. Promotional campaign products (fact sheets, brochures, scripts for messages, and public service announcements) are being developed, and existing bilingual health education materials will also be utilized.

RECOMMENDATIONS: The Board members praised the investigators for the large amount of work accomplished in a short period of time, noting their high level of commitment and enthusiasm for the study. The following recommendations were made:

1. The Board unanimously approved the study protocol and continuation.
2. The Board requests more information about Dr. Allison's ancillary study proposal: how

participants will be selected for participation, when and how participants will be informed about and invited to participate in the ancillary study, what alert values and procedures will be followed to inform participants and their health care providers about hemodynamically significant findings, and what advice for follow-up will be given.

3. The following documents should be sent to the Board for review as soon as available and well before recruitment begins: specific study enrollment exclusion criteria; electrocardiogram, pulmonary function testing, oral examination protocols; and a complete list of alert values and referral guidelines presented in a table format similar to that used during the meeting presentation. The Board will review and provide comments on these documents within 3 weeks after their receipt.
4. The consent form should include a statement that interviews may be recorded for quality control purposes but that the participant may refuse to have this done.
5. At all field centers, accommodations should be made for deaf participants by providing or enabling sign language interpreters.
6. The dental exam protocol and dental hygienist training should include oral cancer screening.
7. The study should make an effort to determine normal expected values for lung function in Latinos from the various regions of origin.
8. As a safety measure, use of a glucometer should be incorporated into the standard protocol to prevent oral glucose tolerance tests from being administered to undiagnosed diabetics.

In addition, the Board offered the following suggestions for the investigators:

1. For the hearing exam component, add as an alert value an average hearing threshold difference between the ears of ≥20 dB HL.
2. For each ancillary study proposal, please provide the OSMB access to an ancillary studies tracking system, a reminder of previously approved ancillary studies on the same or a related topic, and a description of current and potential added time burden to participants.
3. Consider re-evaluating the level of reimbursement for participation and participation rates, with a possible mid-course adjustment of the amount reimbursed. Establish a process to capture persons screened who are willing to participate but are unable due to work.
4. Review the hearing exam interview; replace medical terms with better understood lay terms.
5. Order questionnaires in clusters that have similar time periods of inquiry (e.g., the past 30 days, the past year, etc.).
6. Provide space on the consent form for a witness signature for those unable to read or write.

NEXT MEETING: The next meeting of the OSMB is tentatively planned for March, 2008. The Coordinating Center will poll members for their availability to determine an exact date.

SIGNATURES

Respectfully submitted,

/s 7/5/2007 /s 7/5/2007

George Howard, Ph.D. Jean Olson, M.D., M.P.H.
Acting Chair, HCHS-SOL OSMB Executive Secretary, HCHS-SOL OSMB

_____ APPROVAL _____ DISAPPROVAL

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Deputy Director, NHLBI Date