MINUTES
Observational Study Monitoring Board
Atherosclerosis Risk in Communities
Meeting, December 4, 2013

PARTICIPANTS:

OSMB Members Present: Jerome Rotter (phone), Robert Goldberg, Tommy Wang, Julie Buring, Mary Haan

NHLBI: Cashell Jaquish, Jacqueline Wright, Cheryl Jennings, Jean Olson (acting Chair OSMB), Paul Sorlie, Lucy Hsu

OSMB absent: Veronique Roger (Chair), Oscar Lopez

Investigators: Alvaro Alonso,Christie Ballantyne, Eric Boerwinkle, Josef Coresh, David Couper, Aaron Folsom,Mike Griswold, Rebecca Gottesman, Gerardo Heiss, Ron Hoogeveen, Silvana Lawvere, Pamela Lutsey, Kunihiro Matsushita, Tom Mosley, Kim Ring, Amil Shah,Sally Stearns, AndreaRawlings, Wayne Rosamond,Richey Sharrett, GwenWindham, Lisa Wruck

INTRODUCTION (closed section): Dr. Olson called the meeting to order at 8:30 am.Minutes from the November 28, 2012 meeting were discussed and approved.Dr. Wright gave the Project Office Reportand thanked the Board for input on ancillary studiesand adverse events. Dr. Wright reviewed the structure of the study and centers,aims for the current contract and the Neurocognitive Study (NCS) ancillary study, and noted that Visit 5 is complete. She mentioned that given the large number of ancillary studies, there may be a need to coordinate multiple contacts with participants. Dr. Wright mentioned that the study is in the process of switching systems used for surveillance and she summarized progress in health economics research at the CORC. Progress in the NCS was reviewed.The Board found the investigators' responses to the 2012recommendations satisfactory.

OPEN SESSION:

Visit 5 and Annual Follow up:
Dr. Folsom presented an overview of study design, exam progress, surveillance, publications and ancillary studies. Community surveillance of coronary heart disease (CHD) and heart failure (HF) for 2011 are on target for completion by December 2013. Exam 5 wascompleted with 65% of the surviving cohort completing exams either in clinic or at home. The exam was completed in concert with exams for the NCS includingdetailed cognitive testing and Brain MRI on a subset.The ARIC Study investigators authored 147 publications in 2013 with several in high impact journals. The ARIC study provides a platform for 166 funded ancillary studies, including 98 active ancillary studies with many more in review or in development.

Questions were raised regarding tracking an individual participant's burden. Coordination of follow-up contacts is an important issue and multiple contactsin a short time period should be avoided.In addition, the Board suggested that the investigators may want to consider more home visits as theparticipants age or adapting measures to be done in the home.

Dr. Couper gave an update on exam 5 showing the study completed exams on 6,538 participants, with excellent completion rates. He also presentedresults of a study to test comparability of lab assays across visits.Using plasma samples from each visit, results indicated calibration is recommended in longitudinal analysis for some analytes to account for changes in assays.Dr. Heiss reported on cohort retention and follow up and participant safety. Follow-up calls are now twice yearly and non-response was low through contact year (CY) 21. Response rates have dropped from 91% in CY21 to 86% in CY24. The Steering Committee is carefully monitoring retention and investigating sources of non-response. Dr. Heiss also updated the board on reporting of results to participants and participant safety measures such as alerts reporting and monitoring of minor and serious adverse events.

Community and Cohort Surveillance Report:
Dr. Rosamond updated us on community and cohort surveillance activities including trainings abstraction, classification, trends reports and publications. Abstraction and data checks are complete for 100% of CHD and HF community surveillance with 99% classified. Abstraction iscomplete for the cohort for CHD, HF, and stroke, with data checks complete for 99%, and classification complete for 95%. New trend reports include age specific trends for CHD and new methods for defining HF with reduced ejection fraction (EF) and HF with preserved EF.There were 5 community surveillance manuscripts published in 2013 and 20 currently active manuscript proposals, with 6 new lead authors since 2012.

Cardiovascular Outcomes Research Center (CORC) Report: Dr. Stearns reported on the CORC productivity and presented a "behavioral" economics analysis on predictors of self-reported medication adherence with results suggesting that non-adherence was greater for persons who were younger, African American, of low socioeconomic status, or who had diabetes.

Echocardiography Reading Center Report: Dr Shah gave an update on the Center's progress and recent results.The echo center has read over 6,200 echocardiograms and transferred data to the Coordinating Center. Images were of high quality with little missing data.Intra-reader variability was low with very low coefficient of variation for most measures. The echo center has one published design manuscript and several others in preparation with abstracts already presented for many, focusing on normative values in elderly, prevalence and correlates of dysfunction and cardiac structure/functionand prevalent disease.

Neurocognitive Study (NCS): Dr. Mosley presented an update on the NCS which conducted a comprehensive battery of cognitive tests on 6,538 Exam 5 participants with brain MRI on1,950 participants with only about 20 left to complete.

Laboratory Report: Dr. Ballantyne presented an update on atherosclerosis laboratory activities, including support of Exam 5, support of ancillary studies involving stored specimens and measurements conducted for the calibration study described by Dr Couper. The lab completed specimen processing and assay measurement on 7,550 specimens (including blinded QC specimens). The lab completed analysis of hscTnT in batch following approval of an agreement with Roche Laboratories for use of the assay. The lab maintains a freezer farm consisting of over 70 freezers containing over 1.7 million vials from ARIC Exams 1-5 and the ARIC Carotid MRI Study and maintains CAP and CLIA accreditation.Dr. Boerwinkle presented an overview of genomics in ARIC. ARIC has played a lead role in genomics consortia. He discussed a scientific commons approach for future analysesrather than further meta-analysis.

Scientific Presentations:

Dr. Windham discussed predictors of physical function. Dr. Lutsey presented results of a studyon the relationship between serum 25-hydroxyvitamin D and incident heart failure.Dr. Rawlings reported on the association between diabetes in midlife and 20-year cognitive decline.Dr. Matsushita discussed the relationship between kidney disease measuresand left-sided cardiac structure. Dr. Ballantyne presented results from a study on carotid artery plaque burden (MRI) and incident CVD.

CLOSED SESSION

Recommendations:

1. **The Board commends ARIC on the productivity and quality of publications, completion of Exam 5 and the extensive and productive collaborations. The Board specifically commends them on the work of the Echo Center, involvement of junior investigators and the genetic research.The Board recommends continuation of the study during this contract period and beyond.**
2. **The rising incidence of heart failure is an important problem,and the Board encourages novel approaches forstudying the etiology of this rise.**
3. **Dr. Rosamond has done an excellent job with surveillance. Perhaps he could consider a small feasibility study on use of EMR data for surveillance.**
4. **To avoid selection bias as the cohort ages,the Board recommends considering adaptations for increased measures in the home in the NCS renewal. The budget should reflect the possibility of increased numbers of home measures.**
5. **The Board supports the active Ancillary Studies and recommends active monitoring of the individual patient burden – time, visits and calls/contact.The investigators should evaluate the relationship between ancillary study participation and drop out.The Board would like to see the number of participants enrolled in 1, 2, 3, etc. ancillary studies as well as a list of active ancillary studies with no burden, burden in an existing exam or burden in a separate exam specific to the ancillary study.**
6. **The Board recognizes the difficulty of linking to CMS data. The health economics/outcomes research portion is not as productive as expected. It is not clear if this is because of the inherent difficulty or resources. The Board would like to see a list of proposed CORC manuscripts as well as evidence of active collaboration with other ARIC centers.**
7. **The Board encourages the investigators to start to think about embedding small focused RCTs in ARIC in the future.**

Next meeting: Thursday December 4, 2014

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December 23, 2013

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Deputy Director, NHLBI Date