ARIC Manuscript Proposal # 901

PC Reviewed: 07/16/02    Status: __A__    Priority: __2__
SC Reviewed: 07/19/02    Status: __A__    Priority: __2__

1.a. Full Title: Pooling Studies for Risk Prediction of Coronary Heart Disease

b. Abbreviated Title (Length 26 characters):

2. Writing Group (list individual with lead responsibility first):

   Lead: Sean Coady, MA
   Address: National Heart, Lung, and Blood Institute
            II Rockledge Center
            6701 Rockledge Drive; MSC: 7934
            Bethesda, MD 20892
   Phone: (301) 435-1289    Fax: 
   E-mail: coadys@nhlbi.nih.gov

   Writing group members: Lloyd Chambless, Richard Kronmal, Ralph D’Agostino,
                          Willam Kannel, Dan Levy, Lisa Sullivan, Richard Fabsitz, Jean Olson, Paul Sorlie, Elisa
                          Lee

3. Timeline: Plan analytical design and assemble data – 6 months
   Conduct and verify analysis – 6 months
   Prepare, modify and publish paper – 1 year

4. Rationale: The primary objective of this manuscript is to provide a clinically meaningful
   update of the Framingham risk equation using a diverse set of population based prospective
   studies. The principal output being a manuscript with a set of tables, spreadsheets, and/or
   internet applications for use by clinicians appropriate for different age, racial or ethnic
   groups. A recent paper by D’Agostino, et. al. (Validation of the Framingham coronary
   heart disease prediction scores, Results of a Multiple Ethnic Groups Investigation, JAMA
   2001;286:180-187) has shown that the Framingham risk score for CHD is very similar to
   other white populations in the U.S., differs for some variables in black populations and
   differs more for American Indian populations. Thus, to enhance the credibility, utility and
   validity of the coronary risk prediction equations, the studies listed above will be combined
   (in valid ways to be determined by the working group), so that the equations will be based
   on a wider geographical dispersion and age ranges, and will be applicable to whites, blacks
   and American Indians.

5. Main Hypothesis/Study Questions: This study will not test hypotheses regarding
   differences among the studies (which was done in the paper described above), but will
   construct valid CHD prediction equations combining data from each of the studies listed
   above.
6. Data (variables, time window, source, inclusions/exclusions): Each study will provide data on the CHD endpoint (MI or CHD death), data to exclude the prevalent disease to determine the population at risk, data regarding length of follow-up and intervals between risk factor assessment, and data on risk factors. At the present time the requirements are for age, sex, race, SBP, DBP, anti-hypertensive medications, total cholesterol, LDL cholesterol, HDL cholesterol, cholesterol lower medications, cigarette smoking (status, quantity and duration), diabetes (diagnosis, treatment), blood glucose (casual, fasting or challenged). Though subject to further evaluation, the following variables are not to be included in the analyses: BMI (effects mediated through other variables), urine albumin and creatinine (not available in some studies), ECG-LVH, family history (recall has bias, and in ARIC not shown to be an independent contributor), fibrinogen (not yet ready for modification), and Lp(a) (some independent effects in ARIC but uncertain implications for treatment, different measurement techniques). Analyses will be conducted at the NHLBI under the direction of the working group.

7.a. Will the data be used for non-CVD analysis in this manuscript? ___ Yes ___x__ No

7.b. If Yes, is the author aware that the file ICTDER02 must be used to exclude persons with a value RES_OTH = “CVD Research” for non-DNA analysis, and for DNA analysis RES_DNA = “CVD Research” would be used? ___ Yes ___x__ No
(This file ICTDER02 has been distributed to ARIC PIs, and contains the responses to consent updates related to stored sample use for research.)

8.a. Will the DNA data be used in this manuscript? ___x__ Yes ___x__ No

8.b. If yes, is the author aware that either DNA data distributed by the Coordinating Center must be used, or the file ICTDER02 must be used to exclude those with value RES_DNA = “No use/storage DNA”? ___x__ Yes ___x__ No

9. The lead author of this manuscript proposal has reviewed the list of existing ARIC Study manuscript proposals and has found no overlap between this proposal and previously approved manuscript proposals either published or still in active status. ARIC Investigators have access to the publications lists under the Study Members Area of the web site at: [http://bios.unc.edu/units/csc/ARIC/stdy/studymem.html](http://bios.unc.edu/units/csc/ARIC/stdy/studymem.html)

___x__ Yes _______ No

10. What are the most related manuscript proposals in ARIC (authors are encouraged to contact lead authors of these proposals for comments on the new proposal or collaboration)?

Ms611 includes a similar risk prediction equation based on ARIC data alone, but that overlap is not considered to be a problem.