ARIC Manuscript Proposal # 899 (Revised)

PC Reviewed: 09/10/02	**Status: __A__**	**Priority: __2__**
SC Reviewed: 09/13/02	**Status: __A__**	**Priority: __2__**

1.a. Full Title: Do Traditional and Non-Traditional Risk Factors Remain Predictive of Cardiovascular Disease in Chronic Kidney Disease?

b. Abbreviated Title (Length 26 characters): CVD risk factors in Chronic Kidney Disease

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

Lead: Paul Muntner
Address:
Tulane University SPHTM
Department of Epidemiology
1430 Tulane Avenue, SL-18
New Orleans, LA 70112

Phone: (504) 988-1047 Fax: (504) 988-1568
E-mail: pmuntner@tulane.edu
Writing group members: Jiang He, Josef Coresh, Brad Astor, Aaron Folsom

3. Timeline: Only previously collected data will be used. Therefore, we anticipate initiating data analysis in Fall 2002 by preparing an abstract for the Epidemiology council of the American Heart Association. A manuscript will be drafted in late 2002 and early 2003. A final manuscript will be prepared and submitted to the ARIC publications committee after the feedback and comments are received at the AHA epidemiology council meeting in March 2003.

4. Rationale: Compared to the general population, the risk of CVD is higher among patients with chronic kidney disease. Additionally, these patients have poor CVD risk profiles. However, it has been questioned whether CVD risk factors in the general population remain predictive of CVD incidence among patients with chronic kidney disease.

5. Main Hypothesis/Study Questions: Do the same risk factors for CVD among the general population remain predictive among patients with chronic kidney disease? Specifically, what is the association between systolic blood pressure, cigarette smoking, body mass index, waist-to-hip ratio, alcohol consumption, physical activity, diabetes mellitus, HDL, LDL, and total cholesterol, hormone replacement therapy, and sex with cardiovascular disease incidence among patients with chronic kidney disease. Additional non-traditional CVD risk factors will include homocystein, fibrinogen, C-reactive protein, serum albumin, von Willebrand Factor, and white blood cell count. *Furthermore,*

differences in the risk associated with these factors among persons with and without CKD will be explored using tests for interaction.

6. Data (variables, time window, source, inclusions/exclusions):

Baseline and visit 2 creatinine will be used to estimate glomerular filtration rate to define chronic kidney disease. Additional variables to be collected include traditional cardiovascular disease risk factors (HDL, LDL, total cholesterol, diabetes status, smoking, alcohol consumption, blood pressure, body mass index) age, race, and sex and potential confounders. Outcome data will include CVD incidence and mortality, and if power permits coronary heart disease incidence and mortality. This analysis will be limited to ARIC participants with renal impairment. The formal definition of chronic kidney disease set forth by the National Kidney Foundation is an estimated glomerular filtration rate between 30 and 60 ml/min/1.73m2. To enhance our statistical power, we will include persons with an estimated GFR< 70 (n~2000). Preliminary estimates indicate approximately 240 events occurred in this population through 1995. Based on these crude estimates, we have > 80% statistical power to detect a relative risk of 1.75 between the highest and lowest quartiles. We anticipate longer follow-up and therefore greater statistical power. Finally, if power permits, we will repeat all analyses using all ARIC participants meeting the NKF definition for CKD. Based on power calculations, limiting our analyses to persons with an estimated GFR < 60 ml/min/1.73 m2, we will have 80% power to detect a relative risk of 2.0 between any two quartiles of a risk factor given an CVD cumulative incidence of 15% during follow-up. *Although we anticipate limited power, effect modification associated with CKD will be assessed for the traditional and non-traditional risk factors under study.*

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

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 ____ 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? ____ 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"? ____ Yes ____ 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/cscc/ARIC/stdy/studymem.html

_____ 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)?

The most related manuscript "Nontraditional risk factors for coronary heart disease incidence among persons with diabetes: the Atherosclerosis Risk in Communities (ARIC) Study." Dr. Folsom, the second author on that manuscript will collaborate on this study. Additionally, Dr. Josef Coresh, a collaborator on many of the renal disease investigations in ARIC will collaborate on the current proposal.