ARIC Manuscript Proposal #1922

PC Reviewed: 3/20/12	**Status: A**	**Priority: 2**
SC Reviewed: _____	**Status: _____**	**Priority: ____**

1.a. Full Title: Design of a multicenter echocardiographic study to assess the relationship between cardiac structure and function and heart failure risk in free-living elderly subjects: The Atherosclerosis Risk in Communities (ARIC) study.

b. Abbreviated Title (Length 26 characters): **ARIC Echo design**

2. Writing Group:

Writing group members: Amil M Shah, Dalane Kitzman, Ervin Fox, Ken Bulter, Kunihiro Matsushita, Suma Konety, Aaron Folsom, Jose Rivero, Scott D. Solomon; Others welcome.

I, the first author, confirm that all the coauthors have given their approval for this manuscript proposal. _AS__ **[please confirm with your initials electronically or in writing]**

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ARIC author to be contacted if there are questions about the manuscript and the first author does not respond or cannot be located (this must be an ARIC investigator).

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3. Timeline:

Manuscript preparation will begin once this manuscript proposal is approved. Anticipate manuscript completion in approximately the following 3 months.

4. Rationale:

Heart failure (HF) is a critical public health concern afflicting 5 million Americans, especially persons over 65 years of age. Within the aging population, women and African Americans are critically understudied populations that carry a sizeable portion of the HF burden. Progress has been limited in these populations because the epidemiology and treatment of HF in both groups have been understudied. A better understanding of the differences in cardiac structure and function through the spectrum of HF stages generally, and between genders and racial/ethnic groups specifically, will deepen our understanding of the pathophysiology driving HF progression in these populations and may inform novel therapeutic strategies. The NHLBI Atherosclerosis Risk in Communities (ARIC) study presents a unique opportunity to investigate perturbations in cardiac structure and function across the spectrum of HF risk, their relationship to clinical outcomes, and whether they vary in these critically understudied populations. A comprehensive description of the rationale for, design of, and methods of echocardiography during the fifth visit in ARIC will serve as a key reference for future manuscripts employing echocardiographic data.

5. Main Hypothesis/Study Questions:

The proposed manuscript aims to describe the design and methodologies of echocardiography in ARIC at Visit 5, as opposed to testing a specific hypothesis. This manuscript will serve as a foundation and reference for future manuscripts employing echocardiographic data from ARIC Visit 5.

6. Design and analysis (study design, inclusion/exclusion, outcome and other variables of interest with specific reference to the time of their collection, summary of data analysis, and any anticipated methodologic limitations or challenges if present).

This design and methods paper will describe:

(1) The overarching scientific rationale for incorporating comprehensive echocardiography in the ARIC Visit 5
(2) The echocardiography acquisition protocol, including details regarding sonographer training, echo equipment, and study storage media
(3) Image analysis procedures, including quantitative conventional and deformational measures being performed, qualitative assessments performed by cardiologist over-readers, and data management and transfer procedures
(4) Quality assurance protocols, including baseline data on inter- and intra-reader reproducibility for key conventional and deformation measures

The description of the study design and methods will be based on existing documentation, including (1) the Echocardiography Reading Center Manual of Operations, (2) the Field Center Echocardiography Manual of Operations, (3) Echo Reading Center inter- and intra-observer reproducibility data contained in Reading Center monthly reports to the Data Coordinating Center, (4) Echocardiography Reading Center Summary of Review and Research Recommendations in Heart Failure.

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 ICTDER03 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 ICTDER03 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 ICTDER03 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://www.cscc.unc.edu/ARIC/search.php

__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)?

None.

11.a. Is this manuscript proposal associated with any ARIC ancillary studies or use any ancillary study data? ____ Yes __x__ No

11.b. If yes, is the proposal
___ A. primarily the result of an ancillary study (list number* _____)
___ B. primarily based on ARIC data with ancillary data playing a minor role (usually control variables; list number(s)* _____ _____ _____)

*ancillary studies are listed by number at http://www.cscc.unc.edu/aric/forms/

12. Manuscript preparation is expected to be completed in one to three years. If a manuscript is not submitted for ARIC review at the end of the 3-years from the date of the approval, the manuscript proposal will expire.