## **ARIC Manuscript Proposal #2716**

PC Reviewed: 3/8/16	Status: <u>A</u>	Priority: <u>2</u>
SC Reviewed:	Status:	Priority:

**1.a. Full Title**: Diet and cardiovascular disease, diabetes, the metabolic syndrome and obesity: reviewing three decades of research from the ARIC Study

## b. Abbreviated Title (Length 26 characters): Review of ARIC dietary research

## 2. Writing Group:

Writing group members:

Margaret R. Savoca, PhD is a Research Fellow at the Wake Forest School of Medicine in the Department of Epidemiology and Prevention and has extensive experience examining dietary intake and eating behavior in relation to chronic disease and older adults.

Lyn Steffen, PhD, MPH, RD is Associate Professor at the University of Minnesota, School of Public Health, Department of Epidemiology & Community Health. She is the Chair of the ARIC Nutrition Working Group.

Lynne Wagenknecht, Dr.P.H. is Professor and Associate Director of the Division of Public Health Sciences. She is the PI of the ARIC Forsyth County Field Center.

Alain Bertoni, MD, MS is Professor and Chair of the Department of Epidemiology and Prevention and an investigator in the ARIC study.

I, the first author, confirm that all the coauthors have given their approval for this manuscript proposal. \_\_\_MRS\_\_ [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:

Data analysis: 2 months for analysis (Savoca) Further review of findings: 2 months First draft of the paper: 2 months Co-author review/revisions: 1-2 months

# 4. Rationale:

The ARIC Cohort Study was designed to expand our knowledge of risk factors and clinical outcomes of cardiovascular disease (CVD) experienced by Americans as they age.<sup>1, 2</sup> The three waves of ARIC dietary assessments spanned five years of participants' lives and beginning in 1992, provided the foundation for approximately 100 reports.<sup>3-99</sup> ARIC nutrition research has used a wide range of variables to assess the relationship between food and health. These have included dietary biomarkers, estimated intake of micro and macro nutrients, food components and groups, composite food scores, meal patterns, and food environment characteristics. CVD and related conditions, such as diabetes, and metabolic syndrome (MetS), have been associated with diet using prevalence, mortality and hospitalization data, behavioral assessments, clinical measures of disease and metabolism, cellular studies, and genomics. Now in its third decade, ARIC's dietary research parallels the time period when nutrition science was expanding its focus beyond medical nutrition therapy to include nutritional epidemiology with an emphasis on the role of diet in health and the development of chronic disease.<sup>100</sup>

Since the 1980's when ARIC began, the relationships among diabetes, MetS and CVD were established.<sup>101</sup> In this same period, US obesity rates rose from 23% in the late 80's to 36% in 2011-2015.<sup>102</sup> This paralleled dramatic increases in the number of Americans with diagnosed diabetes. Between 1980 and 2014, the number of US adults with diabetes increased from 5.5 million to 22.0 million.<sup>103</sup> By 2011, 63% of the adult incident cases of diabetes were diagnosed between the ages of 40 and 64 years; similar to the age range of ARIC participants when they were enrolled.<sup>104</sup> Overall rate of MetS declined from 26% in 1999-2000 to 23% in 2009-2010 due to improvements in blood pressure, triglycerides and HDL; however, rates of hyperglycemia and elevated waist circumference increased.<sup>105</sup> Heart disease mortality declined in this period, yet it is still the number one cause of US deaths accounting for one of three deaths.<sup>106</sup> ARIC dietary research offers important insights on the sub-optimal dietary patterns linked to these chronic conditions. When viewed as a whole, ARIC nutrition research can provide guidance for public health and clinical research initiatives to reduce the risk of and manage chronic diseases. This review provides an opportunity to review the ARIC dietary measures; highlight key findings about the association between diet and diabetes, CVD, MetS, and obesity; and consider future directions for ARIC nutrition research.

# 5. Main Hypothesis/Study Questions:

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- 1. Describe the methods used for ARIC dietary investigations.
- 2. Trace the changes in approaches and methods in dietary investigation in ARIC over three decades.
- 3. Discuss future directions for ARIC dietary research.

# 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).

The analysis for this review will use a qualitative approach which will include:

- (Lead Author) Identify ARIC reports that include dietary variables as a predictor (independent variables) and clinical outcomes and risk factors for CVD, diabetes, or MetS (dependent variables). Reports where diet is used as a covariate will not be included. The primary resources will be the ARIC Publication database and PubMed.
- 2. (Lead Author) Create an Access database which will permit the storage, sorting, and retrieval of the report (case) summary grid for the analysis. Capture the sample characteristics and exclusions, the dietary measure(s), outcome measures, statistical method, results, and comments for each case.
- 3. (Lead Author) Organize dietary measures and outcomes into broad categories. Cases will be labeled by these categories.
- 4. (Lead Author) Prepare category summaries for dietary measures and outcomes separately.
- 5. (Writing Group) Review category summaries and identify key findings.
- 6. (Writing Group) Come to a consensus on the key findings and areas where further research is needed.

# 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 ICTDER 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: <u>http://www.cscc.unc.edu/ARIC/search.php</u>

\_\_\_\_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)? See attached Citation List

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/

12a. 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.

**12b. The NIH instituted a Public Access Policy in April, 2008** which ensures that the public has access to the published results of NIH funded research. It is **your responsibility to upload manuscripts to PUBMED Central** whenever the journal does not and be in compliance with this policy. Four files about the public access policy from <a href="http://publicaccess.nih.gov/">http://publicaccess.nih.gov/</a> are posted in <a href="http://www.cscc.unc.edu/aric/index.php">http://publicaccess.nih.gov/</a> are posted in <a href="http://publicaccess.nih.gov/submit\_process\_journals.htm">http://publicaccess.nih.gov/submit\_process\_journals.htm</a> shows you which journals automatically upload articles to PubMed central.

13. Per Data Use Agreement Addendum for the Use of Linked ARIC CMS Data, approved manuscripts using linked ARIC CMS data shall be submitted by the Coordinating Center to CMS for informational purposes prior to publication. Approved manuscripts should be sent to Pingping Wu at CC, at pingping wu@unc.edu. I will be using CMS data in my manuscript \_\_\_\_ Yes \_\_X\_ No.

# References

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