ARIC Manuscript Proposal #2975

PC Reviewed: 5/9/16　　　　**Status: _____**　　　　　**Priority: 2**
SC Reviewed: _____　　　**Status: _____**　　　　　**Priority: ____**

1.a. Full Title: Enhancing the Infrastructure of the Atherosclerosis Risk in Communities (ARIC) Study for Cancer Epidemiology Research: ARIC Cancer

   b. Abbreviated Title (Length 26 characters): ARIC Cancer Study

2.　Writing Group:
　　　Writing group members:
Corinne E. Joshu, John R. Barber, Josef Coresh, David J. Couper, Thomas H. Mosley, Mara Z. Vitolins, Kenneth R. Butler, Heather H. Nelson, Anna E. Prizment, Elizabeth Selvin, Janet A. Tooze, Kala Visvanathan, Leah E. Mechanic, Aaron R. Folsom, Elizabeth A. Platz

I, the first author, confirm that all the coauthors have given their approval for this manuscript proposal. CEJ

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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: 1- 3 months

4. Rationale:
The ARIC Cancer Working Group was established in 2010 to 1) connect investigators with mutual research interests, 2) keep investigators apprised of ongoing cancer studies, and 3) provide feedback on planned and proposed manuscripts and ancillary studies on cancer. In 2011, leadership of the ARIC Cancer Working Group and members from each of the Field Centers and the ARIC Coordinating Center received NCI funding (Core Infrastructure and Methodological Research for Cancer Epidemiology Cohorts) to enhance ARIC's infrastructure to yield a CEC. The goals are to retrospectively ascertain and characterize cancer incidence, recurrence, and progression through 2012 and to prospectively ascertain cancer incidence, recurrence, progression and mortality from 2013 forward. To achieve these goals, we initiated a new cancer-specific participant contact, added questions to existing participant contacts, collected and abstracted cancer-specific medical records, linked with state cancer registries, and abstracted archived hospital discharge summaries and medical records. We recently completed the ARIC Cancer Case file (1987-2012). This manuscript will serve as a detailed reference on ARIC Cancer methods for papers using the updated case files. In addition, we hope to inform the broader cancer epidemiology research community about the unique research opportunities in ARIC.

5. Main Hypothesis/Study Questions: The purpose of this paper is to describe the methods we used to enhance the infrastructure of ARIC for cancer epidemiology research, the ARIC cancer data currently available and how to access them, ARIC's cancer risk factor prevalences (among those without a prevalent cancer at Visit 1) and changes in cancer incidence and mortality rates over time compared with the US population, and opportunities for future research and collaboration in ARIC Cancer.

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).

In this manuscript, we will describe the development of the ARIC Cancer Working Group and the aims of the ARIC Cancer Infrastructure grant. We will describe how we created the 2012 cancer case file including the development and execution of the Follow-up Cancer Questionnaire and the additional cancer questions on the AFU and SAFU, re-linkage with cancer registries, and adjudication of cancer cases. We will provide the cancer counts among consenting ARIC participants through 2012. We will also describe the cancer tissue repository developed for the Washington County field center.

To determine the generalizability of ARIC Cancer data to the US population, we will also estimate the prevalences of cancer risk factors (overweight/obesity, smoking status, alcohol intake, physical inactivity, diagnosed diabetes) jointly by race and sex at Visit 1 (1987-1989), Visit 2 (1990-1992), Visit 3 (1993-1995), Visit 4 (1996-1998), and Visit 5

(2011-2013). We will compare prevalences in ARIC to US data from the National Health and Nutrition Examination Survey at similar time points (Visit 1 vs NHANES III phase I; Visit 2 vs NHANES III phase II; Visit 3 vs NHANES III phase II; Visit 4 vs NHANES 1990-2000; Visit 5 vs NHANES 2011-2012). NHANES estimates will be restricted to the age range of the ARIC study population at each visit and calculated using appropriate survey-weights to account for the complex sampling design, including unequal probabilities of selection, over-sampling, and non-response.

We will also use joinpoint regression to estimate trends in cancer incidence and mortality rates jointly by age (50-64 years, 65-74 years, 75+ years), race, and sex and compare them to trends in the US population. ARIC cancer rates will be binned into ~4 year periods to obtain stable estimates (1987-1992, 1992-1997, 1998-2002, 2003-2007, 2008-2012). US cancer incidence and mortality data can be obtained from SEER*Stat and binned as for the ARIC analysis.

Finally, we will provide a description of the many unique features of ARIC as a cohort and describe how interested investigators can learn more about how to access and use ARIC data.

7.a. Will the data be used for non-CVD analysis in this manuscript? __X__ Yes ____ 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? _X___ 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:
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)?

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

11.b. If yes, is the proposal
   _X__   A. primarily the result of an ancillary study (list number* 2011.07, 1995.04)
   ___   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 http://publicaccess.nih.gov/ are posted in http://www.cscc.unc.edu/aric/index.php, under Publications, Policies & Forms.
http://publicaccess.nih.gov/submit_process_journals.htm shows you which journals automatically upload articles to PubMed central.

13. Per Data Use Agreement Addendum, approved manuscripts using 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 ____ No.