ARIC Manuscript Proposal #1963

PC Reviewed: 7/10/12   **Status:** <u>A</u>   **Priority:** <u>2</u>
SC Reviewed: _____   **Status:** _____   **Priority:** ____

1.a. Full Title: Accuracy of reporting of lipid medication

  b. Abbreviated Title (Length 26 characters): Lipid med accuracy

2. Writing Group:
    Writing group members: Jessica Baitani, MD (MPH student), Aaron Folsom, Christie Ballantyne, Eric Whitsel

I, the first author, confirm that all the coauthors have given their approval for this manuscript proposal. __AF___ **[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).
    Name: **Aaron Folsom**
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3. Timeline: finish by Spring 2013

4. Rationale:

ARIC has asked at each examination about use of antihyperlipidemic medications. The validity of this self-report has not been evaluated, but it can be, since ARIC recorded the names of medications. Furthermore, we can see if the validity differs over time, as statins

came into prominent use. Once source of over-reporting is the use of herbals and other over the counter products that participants think lower lipids but probably do not.

This will be Dr. Baitani's MPH project.

5.   Main Hypothesis/Study Questions:

What is the agreement between self-report of lipid medication use and medication names at the ARIC exams?

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).

Design—Agreement studies, involving visits 1-5

Inclusions—At each exam, we will include all who completed the medication questionnaire completely. Although visit 5 is not complete, we believe this analysis would be ok to do with an incomplete sample, since it seems unlikely that accuracy of reporting would differ between early and late examinees. By the time the paper is finished, the visit 5 dataset may also be nearly complete.

Analysis—We will compute agreement indices. For example, besides computing percent agreement, if we consider a named medication with a Med Code indicating "lipid lowering" as the gold standard, then the sensitivity, specificity and predictive values of self-report will be computed. This will be done for each exam and whether these agreement indices have changed over time/aging will be compared.

We can also examine indices by several characteristics, such as age, sex, ethnicity, education.

In passing, we will describe the time/age trend in prevalence of use of antihyperlipidemics in the cohort and the types of meds used at each exam.

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

_____ Yes   ___x____ 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 identified.

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 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.