ARIC Manuscript Proposal # 3121

PC Reviewed: 2/13/2018 Status: _____ Priority: 2
SC Reviewed: _________ Status: _____ Priority: ____

1.a. Full Title: Periodontal Disease Associated with Rheumatoid Arthritis

b. Abbreviated Title (Length 18 characters): Periodontitis and RA

2. Writing Group:
Writing group members:
Julie Marchesan, Leigh Callahan, Jim Beck, Kevin Moss, Steven Offenbacher, Jerry Molitor, John Preissler.

I, the first author, confirm that all the coauthors have given their approval for this manuscript proposal. ___JM___ [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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We invite ARIC investigator(s) to participate in this manuscript

3. Timeline: About nine months for manuscript draft.
4. **Rationale:** Periodontal infection has long been proposed to be correlated with the presence of systemic disease in general. Both diseases share multiple underlying risk factors and pathophysiological features. Evidence supports a bi-directional relationship between periodontal disease and RA in the clinical setting. Still, no study has evaluated the association of periodontal disease and RA in the ARIC study. Our group has recently developed a new classification for periodontal disease named the periodontal profile classification (PPC) (Morelli et al. J Periodontology 2017). The PPC classification was developed using Latent Class Analysis (LCA) to improve the ability to predict tooth loss and incident periodontal disease, as compared to previous disease classifications (e.g. CDC/AAP). LCA creates unique non-overlapping groups/classes of people. These classes represent groups of people that can be described by generally accepted patterns of periodontal disease classifications found in the general population. Importantly, this is the first periodontal disease classification system includes missing teeth patterns. We have found that these measures are useful definitions of disease for developing risk models for dental outcomes and other conditions. By using this classification system, the group has identified that periodontal disease is independently associated with incident stroke risk when evaluating the ARIC study (Sen et al. Stroke. 2018).

5. **Main Hypothesis/Study Questions:** Periodontal Profile Classes (PPC) are correlated to prevalence/incidence of RA.

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).**

   Our analysis will use PPC as an exposure (in comparison to the traditional CDC/AAP classification) and prevalent/incidence of RA as the outcome. We plan to use age, race/center, sex, diabetes, smoking, dental visits and education as control variables. These variables were collected at ARIC Visit 4 from the Dental Ancillary Study. We plan to replicate our findings of prevalence using the National Health and Nutrition Examination Survey (NHANES). NHANES included full mouth oral examinations in the 2009-2010, 2011-2012 and 2013-2014 examination cycles. Our plan is to combine the three NHANES exam cycles (n=10,000). We feel utilizing both the Dental ARIC and NHANES studies to report the relationship of PPC/IPC and RA will enhance the manuscript.

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)?
There are many manuscript proposals that use dental variables as an exposure including but not limited to #2840, 1859, 492, 687, 861, 730, 827, 858, 913, 915, 929, 995, 1112, 1284, 1892, 2053, 1859.

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* __ 1996.01_)

____  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 ____ X____ Yes  ____ No.