ARIC Manuscript Proposal # 1112

PC Reviewed: _11/22/05_  Status: _____  Priority: ____
SC Reviewed: __________  Status: _____  Priority: ____

1.a. Full Title:
-The Clinical, Microbiological and Host Response Characteristics of the Periodontal Tissue-Biofilm Interface (PBI)

b. Abbreviated Title (Length 26 characters):
Biology of Periodontal Interface

2. Writing Group:
Writing group members: JD Beck, S Barros, C Champagne, E Riche, D Lin

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

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3. Timeline: Data analysis has been started, expected completion of manuscript by 1/2006
4. **Rationale**: This will be the first report which has a comprehensive dataset describing the biology of the periodontal pocket environment on a community-based sample with this large number of subjects. We expect that this manuscript will provide new information to enable a reassessment of nosological definitions for periodontal disease.

5. **Main Hypothesis/Study Questions**: That clinical definitions of periodontal disease should be reconsidered based upon new biological information that permits disease reclassifications that incorporate measures of inflammation, microbial load and host response. Notably, probing depths, rather than attachment loss measurements provide more information for disease classifications. Current definitions of disease use attachment level measurements. Thus, we provide new information that suggest a new disease classification.

6. **Data (variables, time window, source, inclusions/exclusions)**: All subject based variables used are known to influence periodontal disease status including characteristics of age, race, gender, smoking, BMI and diabetes status. This study is not about cardiovascular disease associations or cardiovascular outcomes. It is a cross-sectional descriptive paper that describes the periodontal findings: clinical measures of probing depth and attachment level, bleeding, gingival and plaque indices as they relate to the 1) level of organisms present as determined by DNA checkerboard using whole chromosomal probes (18 organisms), 2)local host inflammatory response as determined by gingival crevicular fluid levels of PGE2 and IL-1β, and 3)serum antibody IgG response to the key oral pathogens determined by checkerboard immunoassay. With these variables new clusters of patient disease categories are defined and models that describe severity for each disease group are presented.

7.a. Will the data be used for non-CVD analysis in this manuscript?  _X___ Yes exclusively   ____ No

   b. If Yes, is the author aware that the file ICTDER02 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 ICTDER02 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 ICTDER02 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)?
   The closest manuscript is 687 by Beck who will be a coauthor

11. a. Is this manuscript proposal associated with any ARIC ancillary studies or use any ancillary study data? Dental Ancillary Study 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/

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.