
b. Abbreviated Title (Length 26 characters): GCF Inflammatory Profiling

2. Writing Group:
Writing group members: Catherine Champagne, Steven Offenbacher, Estelle L. Riché, R. Alan Welborn, Kevin Moss, Russ Levy, and James D. Beck.

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

First author: Catherine Champagne
Address: Center for Oral and Systemic Diseases, School of Dentistry Dental Research Center room 222, CB # 7455 University of North Carolina at Chapel Hill Chapel Hill, NC 27599-7455 Phone: 919-843-2712 Fax: 919-966-7537 E-mail: Catherine_Champagne@dentistry.unc.edu

Corresponding/senior author (if different from first author correspondence will be sent to both the first author & the corresponding author):
Address:

Phone: 
Fax: 
E-mail:

3. Timeline: 2-6 month

4. Rationale: Our objective is to describe a newly developed methodology applied to the analysis of archived serum and gingival crevice fluid (GCF) samples for the characterization of individuals’ oral
and systemic inflammatory profiles. The methodology used is still novel but with time, it will become available to more laboratories and investigators. We obtained exciting and important results based on the analysis of concentration levels of 16 different inflammatory mediators in GCF and serum samples from a subset of 180 participants from the Dental ARIC Ancillary Study. Timely publication of the use of this new methodology is essential and relevant to any field investigating serum analyses of inflammatory mediators.

5. Main Hypothesis/Study Questions: Individuals susceptible to the oral infectious disease, periodontitis, exhibit specific oral and/or systemic inflammatory profiles compared to individuals who are periodontally healthy.

6. Data (variables, time window, source, inclusions/exclusions):
   All dental ARIC participants who provided GCF and serum samples and had a periodontal examination are eligible for this study. Dependent variables will be concentration levels of a panel of 16 cytokines in serum and GCF samples from the Dental Ancillary Study. Independent variables will include clinical measures of periodontitis (pocket depth, bleeding on probing, attachment loss), demographic data (age, sex, race/field center), and some traditional risk factors for periodontal disease (smoking, diabetes, BMI, education).

7.a. Will the data be used for non-CVD analysis in this manuscript?
    _ ✔ Yes    ☐ 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?
    _ ✔ 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   _ ✔ 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  

_____ 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)?  

   MS # 1069: Interleukin-1 beta and prostaglandin E2 levels in gingival crevicular fluid and clinical signs of periodontal disease. The first author is a graduate student, but other authors are involved with this proposal.

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

   ✔ Yes  _____ No

11.b. If yes, is the proposal  

   ✔ 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.