



## Concept Paper Form

<b>Provisional Paper Title:</b> Is the microbial balance of oral biofilms associated with risk for ongoing dental caries
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<b>P.I. Sponsor:</b> Murray Thomson, Jonathan Broadbent
<b>Today's Date:</b> 22/04/2019

### **Objective of the study:**

To investigate, using data from Checkerboard DNA-DNA hybridization analysis of oral biofilm samples taken at age 32, associations of a range of ecologically and clinically important bacterial species in four distinct oral habitats (as well as the effects of site, gender, oral hygiene, smoking) and caries experience through to age 45 years.

Definitions:

Biofilm - a functionally and structurally organized, matrix-enclosed aggregate of microorganisms which adheres to surfaces such as tooth enamel.

Caries - an endogenous, polymicrobial, biofilm-mediated disease which is a consequence of a complex interaction between the dentition, the saliva, the diet, fluoride exposure, preventive oral hygiene behaviours and biofilm composition and processes.

Checkerboard DNA-DNA hybridization (CKB) – a molecular microbiology technique which enables simultaneous determination of the presence of multiple selected bacterial species in multiple microbial specimens.

Microbiota - the microorganisms of a particular site or habitat.

Rationale:

There is a lack of research into associations between ecologically and clinically

important bacterial species in distinct habitats, lifestyle factors and caries experience in population-based birth cohorts. The 'Dunedin Study' data and the CKB analysis results present a rare opportunity to report on associations in a prospective birth cohort.

### **Data analysis methods:**

Comparison of medians, regression modeling, principal component analysis

### **Variables needed at which ages:**

Decayed, Missing, Filled Teeth  
OHI  
Smoking  
Gender  
SES  
Plaque bacteria data

### **Significance of the Study (for theory, research methods or clinical practice):**

To date, this will be the first report of findings of CKB analysis of dental biofilms and caries experience from a large-scale epidemiologic study of adults. This report will form the foundation work with further molecular analysis of plaque samples taken at age 45 and at each assessment stage thereafter. This continued research will contribute to knowledge of caries experience and dental biofilms over the life-course as well as to knowledge of the natural history of dental caries.

### **References:**

Selwitz RH, Ismail AI, Pitts NB. 2007. Dental caries. *The Lancet*. 369(9555):51-59.  
Socransky SS, Haffajee AD, Smith C, Martin L, Haffajee JA, Uzel NG, Goodson JM. 2004. Use of checkerboard DNA–DNA hybridization to study complex microbial ecosystems. *Oral Microbiol Immunol*. 19(6):352-362.  
Takahashi N, Nyvad B. 2010. The role of bacteria in the caries process: Ecological perspectives. *J Dent Res*. 90(3):294-303.  
Wall-Manning GM, Sissons CH, Anderson SA, Lee M. 2002. Checkerboard DNA–DNA hybridisation technology focused on the analysis of gram-positive cariogenic bacteria. *J Microbiol Methods*. 51(3):301-311.

## Data Security Agreement

Provisional Paper Title	
Proposing Author	
Today's Date	

**Please keep one copy for your records and return one to the PI Sponsor**

Please initial your agreement: (customize as necessary)

	I am current on Human Subjects Training [CITI <a href="http://www.citiprogram.org">www.citiprogram.org</a> ] or equivalent.
	My project is covered by the Dunedin Study's ethics approval OR I have /will obtain ethical approval from my home institution (please specify).
	<p>I will treat all data as "restricted" and store in a secure fashion. My computer or laptop is:</p> <ul style="list-style-type: none"> <li>• encrypted (recommended programs are FileVault2 for Macs, and Bitlocker for Windows machines)</li> <li>• password-protected</li> <li>• configured to lock-out after 15 minutes of inactivity AND</li> <li>• has an antivirus client installed as well as being patched regularly.</li> </ul>
	I will not "sync" the data to a mobile device.
	In the event that my laptop with data on it is lost, stolen or hacked, I will immediately contact my PI Sponsor or Study Director, Richie Poulton ( <a href="mailto:richie.poulton@otago.ac.nz">richie.poulton@otago.ac.nz</a> ).
	I will not share the data with anyone, including my students or other collaborators not specifically listed on this concept paper.
	<p>I will not post data online or submit the data file to a journal for them to post.</p> <p><i>Some journals are now requesting the data file as part of the manuscript submission process. The Dunedin Study Members have not given informed consent for unrestricted open access, so we have a managed-access process. Speak to your PI Sponsor or Richie Poulton for strategies for achieving compliance with data-sharing policies of journals.</i></p>
	<p>I will delete all data files from my computer after the project is complete. Collaborators and trainees may not take a data file away from the office.</p> <p>The data remains the property of the Study and cannot be used for further analyses without an approved concept paper for new analyses.</p>

**Signature:** \_\_\_\_\_

## CONCEPT PAPER RESPONSE FORM

**A** To be completed by the proposing author:

Provisional Paper Title	
Proposing Author	
Other Contributors	
Potential Journals	
Today's Date	
Intended Submission Date	

***Please keep one copy for your records and return one to the proposing author***

**B.** To be completed by potential co-authors:

Approved       Not Approved       Let's discuss, I have concerns

Comments:

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Please check your contribution(s) for authorship:

<input type="checkbox"/>	Conceptualizing and designing the longitudinal study
<input type="checkbox"/>	Conceptualizing and collecting one or more variables
<input type="checkbox"/>	Data collection
<input type="checkbox"/>	Conceptualizing and designing this specific paper project
<input type="checkbox"/>	Statistical analyses
<input type="checkbox"/>	Writing
<input type="checkbox"/>	Reviewing manuscript drafts
<input type="checkbox"/>	Final approval before submission for publication
<input type="checkbox"/>	Acknowledgment only, I will not be a co-author

**Signature:** \_\_\_\_\_