

Contact: Sydney Local Health District Human Research Ethics Committee
Concord Repatriation General Hospital
Concord NSW 2139
Telephone: (02) 9767 5622
Email: SLHD-ConcordEthics@health.nsw.gov.au
Local Ref: CH62/6/2021-145



CONCORD
REPATRIATION GENERAL
HOSPITAL

09 November 2021

Dr Divnic-Resnik
The Sydney Dental Hospital
Sydney Local Health District

Dear Dr Divnic-Resnik,

Re: Local reference number: CH62/6/2021-145
REGIS ethics application number: 2021/ETH11808
REGIS project ID number: 2021/PID03044
Project title: Development of lipid-A-based population screening test & chair-side diagnostics for personalised, point-of-care periodontal therapy

Thank you for submitting the above research proposal for single ethical and scientific review. This project was first considered by the Scientific Sub-Committee at its meeting of 15 September 2021 and by the Sydney Local Health District Human Research Ethics Committee – CRGH at its meeting held on 28 October 2021. This Human Research Ethics Committee (HREC) has been accredited by the NSW Ministry of Health as a lead HREC under the model for single ethical and scientific review.

This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

I am pleased to advise that final ethical approval has been granted on the basis of the following:

- The research project meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007) – updated 2018*.

The documents reviewed and approved include:

	VERSION	DATE
Human Research Ethics Application (HREA)	1	03 November 2021
Protocol	2.1	04 November 2021
Research Data Management Plan	2.1	04 November 2021
Flow Chart of the study procedures	1	10 August 2021
SDH Master Code Sheet	2	30 September 2021
WCOH Master Code Sheet	2	30 September 2021
Advertisement	2	30 September 2021
Expression of interest	2	30 September 2021
Invitation letter for students	2	30 September 2021
King's College London Ethics Approval (Noted)	No version	27 November 2020
Master Participation Information Sheet – staff & students	2	04 November 2021

Master Participation Information Sheet – patients	2	04 November 2021
Oral-Dental Health-Related Quality of Life UK	1.1	04 November 2021
Participant Consent Form - staff & students	2.1	04 November 2021
Patient Consent Form	2.1	04 November 2021
Preparation pack for participants	1.1	04 November 2021
Questionnaire	2.1	04 November 2021
Standard of Care for patients with gum disease	2.1	04 November 2021
TGA – PIEZON (Noted)	No version	17 March 2014
Manufacturer’s Declaration of Conformity (Noted)	No version	01 July 2019
Training Pack	1.1	04 November 2021
Visual Analogue Scale	1.1	04 November 2021
WCOH Biobank Confirmation Letter (Noted)	No version	27 July 2021
Safety Data Sheet Air Flow PLUS (Noted)	4	11 May 2016

The HREC has provided ethical and scientific approval for the following sites:

1. The Sydney Dental Hospital, Westmead Hospital

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at any site until you have submitted a Site Specific Assessment (SSA) Form to the Research Governance Officer (RGO) and received separate authorisation from the Chief Executive or delegate at that site.

Please note the following conditions of approval:

1. HREC approval is valid for five (5) years subject to the supply of an annual progress report. The first report should be sent to the HREC by **09/11/2022**. You must also provide an annual report to the HREC upon completion of the study.
2. You will adhere to the study protocol at all times.
3. Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review.
4. You will notify the HREC, giving reasons, if the project is discontinued at a site before the expected date of completion.
5. You will immediately report anything which might warrant review of ethical approval of the project, including unforeseen events that might affect continued ethical acceptability of the project, (including Significant Safety Issues).
6. It is noted that REDCap will be used for secure research data collection, management and storage in the study. Once the REDCap project has been set-up, using the SLHD Master Code Sheet Project, please provide a copy of the REDCap Project Codesheets with a version number and date to the Ethics Committee for review and approval prior to study commencement. Please note, the SLHD Research Data Manager and REDCap Administrator can be contacted for assistance and bookings via [email](#) or [online](#) for consultation if necessary.
7. If you are an University of Sydney Staff/Student or hold an affiliation and you are conducting a Clinical Trial on site at the University of Sydney or The University of Sydney will be the sponsor for your project, please contact the Clinical Trial Risk and Governance Officers via email before you commence your study (clinical-trials.research@sydney.edu.au).
8. HREC approval is granted on the assumption that all students and early career researchers are adequately supervised by the principal and senior investigators on a

project. This supervision would ensure that all privacy concerns are met (including the completion of confidentiality agreements by participating students) and that both students and participants are supported in the conduct of the study in line with the approved research protocol.

9. It is a condition of approval that the investigators follow the relevant jurisdictional public health guidelines in relation to COVID-19 site requirements.

Should you have any queries about the HREC's consideration of your project please contact the Executive Officer - (02) 9767-5622. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the website: <https://www.slhd.nsw.gov.au/concord/Ethics/Ethics.html>

We wish you every success in your research.

Please quote the local reference number at the top of this letter in all correspondence.

Yours sincerely,



Professor David Le Couteur

Chair

Sydney Local Health District Human Research Ethics Committee – CRGH