

ADDRESS FOR ALL CORRESPONDENCE
RESEARCH ETHICS AND GOVERNANCE OFFICE
ROYAL PRINCE ALFRED HOSPITAL

TELEPHONE: (02) 9515 6766
EMAIL: SLHD-RPAethics@health.nsw.gov.au
REFERENCE: X22-0199 & 2022/ETH01250



23 August 2022

This letter constitutes ethical approval only. You must NOT commence this research project at ANY site until you have submitted a Site Specific Assessment Form to the Research Governance Officer and received separate authorisation from the Chief Executive or delegate of that site.

Dear Dr Divnic-Resnik,

Re: Protocol no. X22-0199 & 2022/ETH01250 – “The efficacy of the adjunct use of subgingival air-polishing therapy with erythritol powder during initial non-surgical periodontal therapy of mandibular molar furcation defects.”

The Executive of the Ethics Review Committee, at its meeting of 23 August 2022 considered your correspondence of 8 August 2022. In accordance with the decision made by the Ethics Review Committee, at its meeting of 13 July 2022, ethical approval is granted.

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*.

This approval includes the following:

- HREA (Version number 2, dated 19 July 2022)
- Protocol (Version 2, 7 August 2022)
- Research Protocol Flow Chart (Version 2, 7 August 2022)
- Sample collection protocol (Version 1.0, 27 June 2022)
- Master Advertisement (flyer) (Version 2, 7 August 2022)
- Participant Information Sheet (Master Version 2, 7 August 2022)
- Participant Consent Form (Master Version 2, 7 August 2022)
- Form for Withdrawal of Participation (Master Version 1, 26 June 2022)
- Expression of Interest Form (Master Version 2, 7 August 2022)

- Questionnaire contributing /risk factors (Version 1, 04 May 2022)
- Standard of care (SOC) for patients with periodontitis (Version 1, 29 April 2022)
- Research Data Management Plan (dated 27 June 2022)
- Clinical and Imaging Data (Version1, 26/05/2022)
- Master Code Sheet – SHD (Version 1.0, 26/06/2022)
- Master Code Sheet – WOCH (Version 1.0, 26/06/2022)
- Presence of symptoms Visual Analogue Scale (VAS) (Version 2, 7 August 2022)
- Oral-Dental Health-Related Quality of Life United-Kingdom (OHRQoL) (Version 2, 7 August 2022)
- Glossary of Abbreviations (Version 1, 8 August 2022)
- Imaging manual (Version 1, 11 August 2022)
- Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH) Air Flow PLUS (Version number: 4.0, Revision: 2016-05-11)
- Australian Register of Therapeutic Goods Certificate (ARTG Identifier 221351)
- TFD-007_AUS REV B Declaration of conformity - Dental Products - Australia

You are asked to note the following:

The Committee noted that authorisation will be sought to conduct the study at the following sites:

- The Sydney Dental Hospital (PI: Dr Tihana Divnic-Resnik)
- Westmead Hospital (PI: Dr. Rohan Rodricks)
- It is a requirement of ethics approval that, before its commencement, this clinical trial is registered on a publicly accessible register, such as the Australian New Zealand Clinical Trials Registry or another appropriate international register. The Committee therefore sought details of the Register in which the study has been included and its registration number.
- This approval is valid for **five years**, and the Committee requires that you furnish it with annual reports on the study's progress beginning in **August 2023**. This will be through the submission of a milestone in REGIS.
- This human research ethics committee (HREC) has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review and 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*.

- In accordance with the National Statement, Chapter 4.7, you are reminded that you must seek ethical approval from the HREC of the Aboriginal Health and Medical Research Council (AHMRC) if you intend to use Aboriginal or Torres Strait Islander status in any presentation or publication.
- **Partnering with Consumers***: As per Standard 2 of The National Clinical Trials Governance Framework, you are asked to provide an annual update with your annual progress report (milestone) on the ongoing involvement of consumers in the planning, design, delivery, measurement and evaluation of the trial.
 * Protocol Section 11.3 - During the study, meetings with consumers will be held as results of the trial are analysed at significant timepoints including the 3- and 6-month re-evaluation. The 3- and 6-month evaluation updates should be provided to the Committee as a general amendment via REGIS.
- **Good Clinical Practice (GCP)**: When adding additional sites, it is a condition of approval that the GCP Certificate of Completion be submitted for the principal investigator responsible for the new site.
- You must immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project.
- You must notify the HREC of proposed changes to the research protocol or conduct of the research in the specified format.
- You must notify the HREC and other participating sites, giving reasons, if the project is discontinued at a site before the expected date of completion.

Should you have any queries about the Committee's consideration of your project, please contact me. The Committee's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Sydney Local Health District website.

If you are not using REGIS, a copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The Ethics Review Committee wishes you every success in your research.

Regards,



Sanaa Thomas
Executive Officer
Clinical Trials Sub-committee

For:

Rosemary Carney
Executive Officer
Ethics Review Committee (RPAH Zone)