ADDRESS FOR ALL CORRESPONDENCE
RESEARCH ETHICS AND GOVERNANCE OFFICE
ROYAL PRINCE ALFRED HOSPITAL
CAMPERDOWN NSW 2050

TELEPHONE: (02) 9515 6766
EMAIL: Ethics-RPA@sswahs.nsw.gov.au
REFERENCE: X17-0075 & HREC/17/RPAH/107

NSW GOVERNMENT Health
Sydney
Local Health District

18 July 2017

Prof MA Darendeliler
C/- Dr G Cheung
Orthodontics Department
Level 2, 2 Chalmers Street
Sydney Dental Hospital
SURRY HILLS NSW 2010

Dear Professor Darendeliler,

Re: Protocol No X17-0075 & HREC/17/RPAH/107 - "Randomized clinical trial investigating the airway, facial, dental and skeletal changes from bone anchored and tooth anchored rapid palatal expansion (Hybrid-Hyrax) vs traditional rapid palatal expansion (Hyrax) vs a novel keyless palatal expansion device (Keles)"

The Executive of the Ethics Review Committee, at its meeting of 10 July 2017 considered your correspondence received 7 July 2017. In accordance with the decision made by the Ethics Review Committee, at its meeting of 14 June 2017, ethical approval is granted.

The proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research.*

This approval includes the following:

- NEAF (AU/1/867C211)
- Protocol (Version 1.3, 7 July 2017)
- Investigator's Brochure (Version 1, 5 April 2017)
- Participant Information Sheet for Children (10-12 years) (Version 1.3, 2 July 2017)
- Participant Information Sheet Adolescents (13-16 years) (Version 1.2, 3 July 2017)
- Participant Consent Form (Version 1.2, 3 July 2017)

- Participant Information Sheet Parent/Guardians (Version 1.2, 2 July 2017)
- Parent/Guardian Consent Form (Version 1.2, 3 July 2017)
- Advertisement (Version 1, 5 April 2017)
- Questionnaire 1 (Version 1.1, 5 April 2017)
- Questionnaire 2 (Version 1.1, 5 April 2017)

You are asked to note the following:

- **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.**

  On the basis of this ethics approval, authorisation may be sought to conduct this study within any NSW/QLD/VIC/SA/ACT public health organisation and/or within any private organisation which has entered into an appropriate memorandum of understanding with the Sydney Local Health District, Sydney Local Health Network or the Sydney South West Area Health Service.

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

  - Sydney Dental Hospital
- **This study requires notification to the Therapeutic Goods Administration (TGA) under the Clinical Trials Notification (CTN) Scheme.**
- t 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 four years, and the Committee requires that you furnish it with **quarterly reports** on the study's progress beginning in **November 2017.** If recruitment is ongoing at the conclusion of the four year approval period, a full re-submission will be required. Ethics approval will continue during the re-approval process.
- 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*.

- 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.

- If you or any of your co-investigators are University of Sydney employees or have a conjoint appointment, you are responsible for informing the University's Risk Management Office of this approval, so that you can be appropriately indemnified.

- Where appropriate, the Committee recommends that you consult with your Medical Defence Union to ensure that you are adequately covered for the purposes of conducting this study.

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.

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.

Yours sincerely,

Merela Ghazal
Acting Executive Officer
Ethics Review Committee (RPAH Zone)

HERC\EXCOR\17-07