ADDRESS FOR ALL CORRESPONDENCE
RESEARCH ETHICS AND GOVERNANCE OFFICE
ROYAL PRINCE ALFRED HOSPITAL
CAMPERDOWN NSW 2050
TELEPHONE: (02) 9515 7035
EMAIL: SLHD-RPAEthics@health.nsw.gov.au

REFERENCE: **X21-0042 & 2021/ETH00293**
10.1/MAY21

12 May 2021

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 Professor Spahr,

Re: Protocol no. X21-0042 & 2021/ETH00293 - "A novel in-vivo oral biofilm model using an implant-supported biofilm chamber"

The Executive of the Ethics Review Committee, at its meeting of 12 May 2021 considered your correspondence of 20 April 2021. In accordance with the decision made by the Ethics Review Committee at its meeting of 14 April 2021, ethical approval is granted.

The research project meets the requirements of the National Statement on Ethical Conduct in Human Research.

This approval includes the following:

- HREA (Version 3, 15 April 2021)
- Protocol (Version 2, 13 March 2021)
- Participant Information Sheet (Version 5, 4 May 2021)
- Participant Consent Form (Version 2, 14 March 2021)
- Data Collection Form (Version 1, 14 March 2021)
- Master Code Sheet (Version 1, 14 March 2021)
- Research Data Management Plan (Version 1, 13 March 2021)

You are asked to note the

This study requires notification to the Therapeutic Goods Administration (TGA) under the Clinical Trials Notification (CTN) Scheme.

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

- Sydney Dental Hospital

- 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 **May 2022.** 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.

<u>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.</u>

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

Regards,

Sanaa Thomas
Executive Officer
Clinical Trials Sub-committee (RPAH Zone)

for:

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

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