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

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EMAIL: SLHD-RPAEthics@health.nsw.gov.au
REFERENCE: **X20-0514 & 2020/ETH02202**

Health
Sydney
Local Health District

30 June 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 Dr Saxena,

Re: Protocol no. X20-0514 & 2020/ETH02202 - "Safety and efficacy of biodegradable biliary and pancreatic stents (ARCHIMEDES)"

The Executive of the Ethics Review Committee, at its meeting of 30 June 2021 considered your correspondence of 30 June 2021. In accordance with the decision made by the Ethics Review Committee, at its meeting of 10 March 2021, 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 4, 25 June 2021)
- ARCHIMEDES Product Brochure (January 2017)
- Protocol (Version 4, 29 June 2021)
- Participant Information Sheet/Consent Form (Master Version 4, 29 June 2021)
- Form for Withdrawal of Participation (Master Version 2, 25 June 2021)
- Data Management Plan (Version 1, 20 October 2020)
- Patient Code Sheet (Version 1, 26 October 2020)
- Case Report Form (Version 2, 23 February 2021)
- Radiation Report (6 November 2020)

You are asked to note the following:

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

- Royal Prince Alfred Hospital

- 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 study involves the implantation of an investigational device. It is a requirement of ethics approval that all participants are included in a device tracking register and that arrangements are made for monitoring all participants for the lifetime of the device. Any device incidents must be reported to the Therapeutic Goods Administration and to the Committee.

- This approval is valid for **five years**, and the Committee requires that you furnish it with **quarterly reports** on the study's progress beginning in **October 2021.** 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*.

- **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.

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

Regards,

Kind regards,
Sanaa Thomas
Executive Officer
Clinical Trials Sub-committee

For:

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

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