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: X22-0393 & 2022/ETH02125

Health
Sydney
Local Health District

Re-issued 11 April 2023

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. X22-0393 & 2022/ETH02125 - "Sedation, Temperature and Pressure after Cardiac Arrest and Resuscitation – A Factorial Randomized Trial with Three Interventions (the STEPCARE trial)"

The Executive of the Ethics Review Committee, at its meeting of 4 April 2023 considered your correspondence of 24 February 2023 and of 28 March 2023. In accordance with the decision made by the Ethics Review Committee, at its meeting of 14 December 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*.

- The Committee granted a waiver of the usual requirement of consent for the random assignment of participants that meet the eligibility criteria to strategies for sedation, temperature and blood pressure management. It is noted the approach to obtaining consent will be based on the guidelines in Chapter 4.4.1 of the NHMRC National Statement.

- For participants who pass away before consent has been obtained from the participant or PR/SDM/MTDM, the Committee granted a waiver of the usual requirement of consent to use trial related information.

- The Committee granted a waiver of the usual requirement for the consent of the individual for the use of their health information in a research project, in accordance with the *Health Records and Information Privacy Act 2002* (NSW) and the NSW Privacy Commissioner's Statutory guidelines on research and the NHMRC Guidelines approved under Section 95A of the Privacy Act 1988.

- The trial compares standard therapies and is therefore exempt from referral to the Guardianship Tribunal in NSW.

This approval includes the following:

- HREA (Version 3, 26 January 2023)
- Protocol (Version 1.1, 17 February 2023)
- Protocol Summary of Changes for Protocol Version 1.0, 11 November 2022 to Version 1.1, 17 February 2023
- Appendix 1 Australia Specific Modifications (Version 3.0, 28 March 2023)
- Master Participant Information Sheet and Consent Form (Version 3.0, 28 March 2023)
- Master Person Responsible/Substitute Decision Maker/Medical Treatment Decision Maker Information Sheet and Consent Form (Enrol or Continue) (Version 3.0, 28 March 2023)
- Master Information Brochure (Version 1.0, 16 January 2023)
- SLHD Privacy Compliance Form (28 November 2022)
- Research Data Management Plan (28 March 2023)
- Telephone Script (Version 1.0, 28 November 2022)
- Victorian Specific Module (dated 28 November 2022)
- Curriculum Vitae – Dr A Aneman
- Curriculum Vitae – Prof R Bellomo
- Curriculum Vitae – Dr M Saxena
- Curriculum Vitae – Dr A Ghosh
- Curriculum Vitae – Dr I Seppelt
- Curriculum Vitae – Dr W Stedman
- Curriculum Vitae – Dr J Walsham
- Curriculum Vitae – A/Prof W Cheung
- GCP Certificate – Dr J Walsham (dated 11 November 2019)
- GCP Certificate – A/Prof W Cheung (dated 27 August 2022)
- GCP Certificate – Dr A Aneman (dated 19 October 2021)
- GCP Certificate – Prof R Bellomo (dated 29 October 2021)
- GCP Certificate – Dr M Saxena (dated 03 February 2020)

- GCP Certificate – Dr A Ghosh (dated 21 December 2021)
- GCP Certificate – Dr I Seppelt (dated 15 May 2020)
- GCP Certificate – Dr W Stedman (dated 05 May 2021)

You are asked to note the following:

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

- Concord Repatriation General Hospital, NSW
- Liverpool Hospital, NSW
- Nepean Hospital, NSW
- Royal North Shore Hospital, NSW
- St George Hospital, NSW
- Princess Alexander Hospital, QLD
- Austin Health, VIC
- Northern Hospital, VIC

- 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 **March 2024.** 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.

- **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,

S. Thomas

Sanaa Thomas
Executive Officer
Clinical Trials Sub-committee

For:

Rosemary Carney
Executive Officer
Ethics Review Committee (RPAH Zone)

HERC\EXCOR\23-03