Queensland Government

Metro South Health

Research

Enquiries to: Metro South Human Research Ethics Committee
Telephone: 07 3443 8049
Our Ref: 55203 (SR)
Email: MSH-Ethics@health.qld.gov.au

Dr Danielle Crimmins
Anaesthesia Department
Princess Alexandra Hospital

Dear Dr Crimmins,

HREC Reference number: HREC/2020/QMS/55203
Project Title: PROSPER: Propofol versus sevoflurane pilot study for management of endovascular clot retrieval in ischaemic stroke

Thank you for submitting the above research protocol to the Metro South Human Research Ethics Committee for ethical and scientific review. This protocol was first considered by the Human Research Ethics Committee (HREC) at the meeting held on 6 October 2020.

I am pleased to advise you that the research protocol meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007, updated 2018)* and ethical clearance has been granted. This HREC clearance is valid from 19 November 2020.

You are reminded that this letter constitutes ethical approval only. You must not commence this research protocol at a site until separate authorisation from the Hospital Health Service Chief Executive (CE) or Delegate of that site has been obtained.

A copy of this approval must be submitted to the Research Governance Office(r)/Delegate of the relevant institution with a completed Site Specific Assessment (SSA) Form for authorisation from the CE or Delegate to conduct this research at the Princess Alexandra Hospital.

If this study currently receives grant funding, please remember to forward a copy of this approval letter to the relevant Grants Office of the Administering Institution(s) for the grant.

The documents reviewed and approved include:

Document	Version	Date
HREA Form submitted via Ethical Review Manager (ERM)	Nov ver 2	12.11.2020
Prosper Protocol	2	12.11.2020
PROSPER Case Report Form	1	17.09.2020
CV – Crimmins	N/A	2020
Cover Letter	1	16.09.2020
PROSPER verbal-phone consent form	1	12.11.2020
PROSPER patient information consent form	1	12.11.2020

Ongoing approval is for the duration of the project, conditional on:

1. The HREC approves for a waiver of consent to be given for initial enrolment into the trial and randomisation if a substitute decision maker is not available at the time, as per the approved protocol. However once the participant regains capacity, they must give informed consent to remain in the research study and have their data used for such a purpose.
2. In accordance with Section 5.5.6 (b) of the National Statement, the Principal Investigator will report to the HREC annually (**Due by 30 April each year)** in the specified format with a final report to be submitted on completion of the study.
3. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the protocol in the specified format, including unforeseen events that might affect continued ethical acceptability of the protocol as per the National Health and Medical Research Council's (NHMRC) guidance on *Safety Monitoring and Reporting in Clinical Trials involving Therapeutic Goods (2016)* and its supplementary documents.
4. Amendments to the research protocol which may affect the ongoing ethical acceptability of a protocol must be submitted to the HREC for review electronically via Ethical Review Manager (ERM). Major amendments should be reflected in revised study documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study.
5. Amendments to the research protocol which only affect the ongoing site acceptability of the protocol are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r.
6. Proposed amendments to the research protocol which may affect both the ethical acceptability and site suitability of the protocol must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the Research Governance Office/r.
7. Amendments which do not affect either the ethical acceptability or site acceptability of the protocol (e.g. typographical errors) should be submitted electronically via ERM. These should include a cover letter from the Principal Investigator or Study Co-ordinator providing a brief description of the changes and the rationale for the changes and accompanied by all relevant updated documents with tracked changes.
8. The HREC will be notified, giving reasons, if the protocol is discontinued at a site before the expected date of completion.
9. If you require an extension for your study, please submit a request for an extension in writing outlining the reasons. Note: One of the criteria for granting an extension is the compliance with the approval's conditions including submission of progress reports.
10. Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes (WHO / ICMJE 2008 definition) should be registered, including early phase and late phase clinical trials (phases I-III) in patients or healthy volunteers (WHO Recommendation / ICMJE policy). If in doubt, registration is recommended. All studies must be registered prior to the study's inception, i.e. prospectively. http://www.anzctr.org.au/

Please note: The Metro South HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007, updated 2018), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2018)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. The composition of the Metro South HREC is attached on the final page of this letter.

Should you have any queries about the HREC's consideration of your protocol please contact Ethics Secretariat on 07 3443 8049.

The Metro South HREC wishes you every success in your research.

Yours sincerely,

A/Prof Scott Campbell
Chair
Metro South Hospital and Health Service
Human Research Ethics Committee (EC00167)
Metro South Research
_19_/_11_/_2020_

TO WHOM IT MAY CONCERN

The following is the current composition of the Metro South Human Research Ethics Committee as at 1 January 2020. It is advised that the Committee abides by the guidelines of the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007, updated 2018)*.

COMPOSITION OF METRO SOUTH HUMAN RESEARCH ETHICS COMMITTEE	MEMBER
Category A – Chairperson	Scott Campbell
Category A – Deputy Chairperson	Mary Boyde
Category B - Lay Female	Beverley Kurkowski
Category B - Lay Female	Jaye Buswell
Category B – Lay Female	Judith Wardell
Category B - Lay Male	David Milne
Category C - Knowledge of Professional Care	Kelly Perkins
Category C - Knowledge of Professional Care	Jenny Jones
Category C – Knowledge of Professional Care	Bena Brown
Category C – Knowledge of Professional Care	Lisette Brock
Category C – Knowledge of Professional Care	Megan McKerrow
Category C – Knowledge of Professional Care	Andrew Wheaton
Category C – Knowledge of Professional Care	Melissa Arneil
Category C – Knowledge of Professional Care	Vera Meeusen
Category D – Pastoral Care Role in Community	Bruce Monley
Category D – Pastoral Care Role in Community	Cindy Sinclair
Category D – Pastoral Care Role in Community	David McEwan
Category D – Pastoral Care Role in Community	Trevor Jordan
Category E – Lawyer	John Bennett
Category E – Lawyer	Susan Gardiner
Category F - Knowledge of Research	Adam La Caze
Category F - Knowledge of Research	Marianne Wyder
Category F – Knowledge of Research	Theo Theodoros
Category F - Knowledge of Research	Ayesha Shah
Category F – Knowledge of Research	Nicole Warrington
Category F – Knowledge of Research	Aideen McInerney-Leo
Category F – Knowledge of Research	Dariusz Korczyk
Category F – Knowledge of Research	Rahul Ladwa
Category F – Knowledge of Research	Victoria Atkinson
Category F – Knowledge of Research	Tatiane Yanes
Category F – Knowledge of Research	Shivanand Hebbandi

Should you require further information, please do not hesitate to contact our office on the telephone number listed above. Attendance at the Committee meeting was in accordance with Guidance of the National Statement 5.2.30.