

5th February 2019



Dr L Kennedy
Perinatal Medicine
WCHN

Research Secretariat
Level 2, Samuel Way Building
72 King William Road
North Adelaide SA 5006
Tel 08 8161 6390
Tel 08 8161 6521
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Dear Dr Kennedy

Re: Spinal cord Position in Neonates At Lumbar puncture (SPINAL). Interobserver variability of clinician performed ultrasound to assess the spinal cord termination in neonates. HREC/18/WCHN/163. Ethics expiry date: 28/02/2022.

Lead HREC for the above study for the following institutions/sites:

Women's and Children's Health Network

I refer to your letter dated 8th January 2019 in which you responded to matters raised by the WCHN Human Research Ethics Committee at its 5th December 2018 meeting. I am pleased to advise that your protocol has been granted full ethics approval and meets the requirements of the *National Statement on Ethical Conduct in Human Research*.

Specifically, the following documents have been noted/approved:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Site Specific Consent Form: consent form	1	20 November 2018
Protocol: protocol and description	2	14 January 2019
Patient Information Sheet/Consent Form: info sheet	2	11 January 2019
HREA Application: AU/1/6E49310		20 November 2018
Response to Request for Further Information: Response Letter		08 January 2019

This letter constitutes advice on ethical consideration only. You must not commence this research project at a site until you have obtained separate research governance approval from the site concerned. A copy of this letter should be forwarded to all site investigators for submission to the relevant Research Governance Officer.

At the WCHN, or any other SA Health site, separate authorisation from the Chief Executive or delegate of that site must be obtained through a Site Specific Assessment (SSA) request. For information on this process at the WCHN, please contact the WCHN Research Governance Officer, Ms Camilla Liddy (telephone 8161 6688, email camilla.liddy@sa.gov.au).

I remind you approval is given subject to:

- immediate notification of any serious or unexpected adverse events to participants;
- immediate notification of any unforeseen events that might affect continued ethical acceptability of the project;
- submission of any proposed changes to the original protocol. Changes must be approved by the Committee before they are implemented;
- immediate advice, giving reasons, if the protocol is discontinued before its completion;
- submission of an annual report on the progress of the study, and a final report when it is completed to the WCHN Research Governance Officer. It is your responsibility to provide these reports, without reminder. The proforma for the report may be found on the WCHN Research Governance and Ethics website.

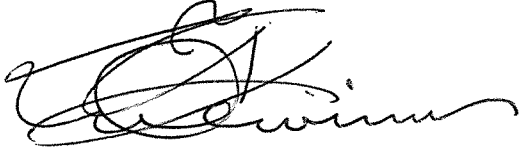


Government
of South Australia

SA Health

Approval is given for three years only. If the study is more prolonged than this, an extension request should be submitted unless there are significant modifications, in which case a new submission may be required. Please note the expiry date in the title above and include it in any future communications.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Tamara Zutlevics', with a large, stylized initial 'T'.

TAMARA ZUTLEVICS (DR)
CHAIR
WCHN HUMAN RESEARCH ETHICS COMMITTEE