

**Contact for this correspondence:**

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27 November 2018

Associate Professor Germaine Wong  
Centre for Kidney Research  
The Children's Hospital at Westmead

Dear A/Prof Wong,

**HREC Reference:** HREC/18/SCHN/325

**Project title:** NAV-KIDS<sup>2</sup> trial: A multicenter, staggered randomized controlled trial in children with chronic kidney disease

**Sites:** The Children's Hospital Westmead  
Sydney Children's Hospital, Randwick

Thank you for submitting the above project for single ethical and scientific review. This project was first considered by the Sydney Children's Hospitals Network Human Research Ethics Committee ("the Committee") at its meeting held on **17 August 2018** and subsequently by the Executive Committee out of session on **22 November 2018** and the Executive out of session on **27 November 2018**.

The HREC has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review, and by the National Health and Medical Research Council as a certified committee in the review of multi-centre clinical research projects.

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and *CPMP/ICH Note for Guidance on Good Clinical Practice*.

I am pleased to advise that, following receipt of the required further information on 20 November 2018 and 26 November 2018, the Committee has granted ethical approval of this research project. Your approval is valid for five (5) years, effective the date of this letter.

This application has been assessed in accordance with, and meets the requirements of the National Statement on Ethical Conduct in Human Research (2007).

The documents reviewed and approved by the Committee are:

<i>Document</i>	<i>Version</i>	<i>Date</i>
NEAF Application Submission code: AU/1/76E739	-	13 July 2018
Cover Letter	-	13 July 2018
Caregiver Satisfaction Questionnaire	V1	28 May 2018
Response to Queries & Additional Documents	-	15 August 2018
Patient Navigator Satisfaction Questionnaire	V1	18 June 2018
Qualitative Interview Guide	-	Rec'd 13 July 2018
NAVMAN - Timeline	-	Rec'd 13 July 2018
Questionnaire	V1	16 May 2018
SCHN Response Letter	-	20 November 2018
Participant Information Sheet and Consent Form	V2	13 November 2018
Navigator Risk Management Plan	V1	Rec'd 20 November 2018
Email from Principal Investigator	-	20 November 2018
Case Report Form - WAIT	V2	13 November 2018
Case Report Form - IMMEDIATE	V2	13 November 2018
Victorian Specific Module	-	13 November 2018
Young Person Information Sheet	V2	13 November 2018
Response Email to Committee	-	26 Nov 2018
Protocol	V3	26 Nov 2018

The documents reviewed and noted by the Committee are:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Australian Kidney Trials Network – Trial Proposal – Review Form	-	Rec'd 13 July 2018
Australian Kidney Trials Network - Scientific Committee Support	-	11 July 2018
Australian Kidney Trials Network – Peer Reviews	-	11 July 2018
Response to the Australian Kidney Trials Network Reviews	-	Rec'd 13 July 2018

Please note the following conditions of approval:

1. The Coordinating Investigator will immediately report anything which may warrant review of ethical approval of the project in accordance with the SCHN adverse event reporting policy.
2. All proposed changes to the research protocol, including the conduct of the research, changes to site or personnel, or an extension to HREC approval, are to be provided to the HREC or its delegate for review before those changes can take effect.

3. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.
4. The co-ordinating investigator will provide an annual report to the HREC on the anniversary of this approval letter, and a final report on completion of the study.
5. Your approval is valid for five (5) years from the date of the final approval letter. If your project extends beyond that five year period and you are still actively recruiting you will be required to resubmit your application incorporating any amendments within six (6) months of that approval expiry date. If your project is in follow up on, or analysis, please submit and application for amendment to extend the approval period. Ethics approval can be extended for a period of twelve (12) months at a time.
6. In the event of a project **not having commenced** within 12 months of its approval, the approval will lapse and reapplication to the HREC will be required.

Should you have any queries about the HREC's consideration of your project please contact the Ethics Administration Assistant on (02) 9845 1253.

**You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.**

The SCHN HREC wishes you every success in your research.

Yours faithfully



Associate Professor Sarah Garnett  
**Chair, Sydney Children's Hospitals Network Human Research Ethics Committee**  
**Sydney Children's Hospitals Network Human Research Ethics Committee**

***NB: All clinical trials must now be registered on a publicly accessible registry such as the Australian New Zealand Clinical Trials Registry. For further information please go to [www.anzctr.org.au](http://www.anzctr.org.au). Please provide this office with a copy of your registration number for our records if you have not already done so.***

CC: Anita Van Zwieten