

**Royal Brisbane & Women's Hospital  
Human Research Ethics Committee**

Enquiries to: Ann-Maree Gordon  
A/Coordinator  
Telephone: 07 3646 5490  
Facsimile: 07 3646 5849  
File Ref: HREC/15/QRBW/500  
Email: [RBWH-Ethics@health.qld.gov.au](mailto:RBWH-Ethics@health.qld.gov.au)

**Metro North  
Hospital and Health Service**

Ms Kathryn Havas  
School of Nursing  
Queensland University of Technology  
Victoria Park Road  
Kelvin Grove Q 4059

Dear Ms Havas,

**Re: Ref N<sup>o</sup>: HREC/15/QRBW/500: A pre-post trial of a person-centred, theory-based intervention to support self-management in chronic kidney disease**

Thank you for submitting the above research project for single ethical review. This project was considered by the Royal Brisbane & Women's Hospital Human Research Ethics Committee (RBWH HREC) (**EC00172**) at its meeting held on 12 October 2015.

I am pleased to advise that the RBWH Human Research Ethics Committee has granted ethical approval of this research project.

The nominated participating site for this project is:

- Metro North Hospital and Health Service (MNHHS) Kidney Health Services (KHS)

Note: If additional sites are engaged prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the RBWH HREC. Notification of withdrawn sites should also be provided to the RBWH HREC in a timely fashion.

**This letter constitutes ethical approval only.** This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site.

The approved documents include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		23 September 2015
Application: NEAF ( <i>Submission Code: AU/1/1B81215</i> )	2.2 (2014)	25 September 2015
Participant Handouts	1	01 September 2015
Clinical Data Collection Sheet	1	28 July 2015
Patient Interview Schedule	1	06 July 2015
Support email from Inala Primary Care	1	09 September 2015
Confirmation of Candidature from Research Degrees Committee	1	20 May 2015
Curriculum Vitae of Kathryn Havas	1	23 September 2015
Response to Request for Further Information		20 October 2015
Protocol	2	16 October 2015
Companion Handbook	2	19 October 2015
Patient Flyer	2	16 October 2015
Clinician Script to inform patients about the study	1	16 October 2015
Participant Information Sheet & Consent Form	2	16 October 2015
Patient Questionnaires	2	16 October 2015

Approval of this project from the RBWH HREC is valid from **26.10.2015** to **26.10.2018** subject to the following conditions being met:

- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Coordinating Principal Investigator will notify the RBWH HREC of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found at <http://www.health.qld.gov.au/rbwh/research/hrec.asp>.
- The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with the RBWH HREC policy and procedures. These instructions can be found at <http://www.health.qld.gov.au/rbwh/research/hrec.asp>.
- In accordance with Section 3.3.22 (b) of the National Statement the Coordinating Principal Investigator will report to the RBWH HREC annually in the specified format, the first report being due on **26.10.2016** and a final report is to be submitted on completion of the study. These instructions can be found at [http://www.health.qld.gov.au/ohmr/html/regu/reporting\\_templates.asp](http://www.health.qld.gov.au/ohmr/html/regu/reporting_templates.asp).

- The Coordinating Principal Investigator will notify the RBWH HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- The Coordinating Principal Investigator will notify the RBWH HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Instructions for obtaining an extension of approval can be found at <http://www.health.qld.gov.au/rbwh/research/hrec.asp>.
- The Coordinating Principal Investigator will notify the RBWH HREC of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.
- A copy of this ethical approval letter together with completed Site Specific Assessment (SSA) and any other requirements must be submitted by all site Principal Investigators to the Research Governance Office at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site/s.
- Should you have any queries about the RBWH HREC's consideration of your project please contact the HREC Coordinator on 07 3646 5490. The RBWH HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from <http://www.health.qld.gov.au/rbwh/research/hrec.asp>.

The RBWH HREC wishes you every success in your research.

Yours sincerely,



Dr Conor Brophy  
**Chairperson RBWH Human Research Ethics Committee**  
Metro North Hospital and Health Service  
26.10.2015

This 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)*. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.