

Enquiries to: Centres For Health Research
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Our Ref: HREC/15/QPAH/455 - SSA/15/QPAH/460
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Professor David Johnson
Princess Alexandra Hospital
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**SSA AUTHORISATION
PRINCESS ALEXANDRA HOSPITAL
METRO SOUTH HOSPITAL AND HEALTH SERVICE**

HREC Reference number: HREC/15/QPAH/455

SSA reference number: SSA/15/QPAH/460

Project title: A randomized Study Investigating the Efficacy, Safety and Tolerability of Acupressure versus sham therapy for improving sleep quality in patients with end-stage kidney disease on haemodialysis

Dear Prof Johnson,

Thank you for submitting your application for authorisation of this project. On the recommendation of the Human Research Ethics Committee (HREC), I am pleased to inform you that approval is granted for your project to proceed at the Princess Alexandra Hospital.

This approval is subject to researcher(s) compliance throughout the duration of the research with certain requirements as outlined in the National Statement on Ethical Conduct in Human Research 2007 and Australian Code for the Responsible Conduct of Research.

The duration of this study approval is up until expiration of the reviewing HREC's approval.

The following conditions apply to this research proposal. These are additional to those conditions imposed by the approving HREC.

1. SAEs: Where serious adverse events (SAEs) are encountered, during the course of the study which may have ethical implications. Research Governance Office must be notified as soon as possible. http://www.health.qld.gov.au/pahospital/research/adverse_events.asp
2. Proposed amendments to the research protocol or conduct of the research which may affect the ongoing ethical acceptability of the project and/or the site acceptability of the project are to be submitted firstly to the HREC for review and then to the research governance office after a HREC decision is made. A copy of the HREC approval/rejection letter must be submitted to the RGO.
3. Lapsed Approval: If the study has not commenced within twelve months approval will lapse requiring resubmission of the study to the approving HREC.

Office
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4. Annual Reviews: All studies are required by the NHMRC to be reviewed annually and reported to the relevant HREC within the 12 month reviewing period. The MS HREC Annual Report template is accessed through the MS HREC website
<http://www.health.qld.gov.au/pahospital/research/monitoring.asp>
5. Ongoing duty of care must be followed regarding confidentiality of public information and patient privacy, when research involves the recruitment of Metro South Hospital and Health Service (MSHHS) patients. You are required to comply at all times the Australian and Queensland Laws including the Health Services Act, the Privacy Act, Public Health Act (2005) and other relevant legislation, ethics obligations and guidelines which are applicable to the MSHHS including any requirement in respect of the maintenance, preservation or destruction of patient records.

We wish you every success in undertaking this research.

Yours sincerely,



Prof Ken Ho,
Chair, Centres for Health Research
METRO SOUTH HEALTH

1, 9, 15

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