The Sydney children's Hospitals Network
care, advocacy, research, education

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28 November 2017

A/Prof Patrina Caldwell
Nephrology
The Children's Hospital at Westmead

Dear A/Prof Caldwell,

HREC Reference: **HREC/17/SCHN/384**

Project title: **A study of the effects of transcutaneous electrical nerve stimulation (TENS) on psychosocial and incontinence outcomes in children with overactive bladder syndrome**

Sites: **The Children's Hospital at Westmead**
John Hunter Children's Hospital, Newcastle

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 **20 October 2017** and subsequently by the Executive of SCHN HREC on the **6 November 2017** and on the **27 November 2017**.

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 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:

Document	*Version*	*Date*
TENS study diary	V1	June 2017
TENS Protocol	V2	September 2017
SDQ_4-10 SingleSide		September 2017
SDQ_11-17 SingleSide		September 2017
QOL questionnaire	V1	June 2017
Patrina Caldwell CV		2016
Patient Contact Details	V1	June 2017
Parent Information Sheet	V4	November 2017
NEAF Submission code: AU/1/7580311		13 September 2017
ICIQ-UK questionnaire	V1	September 2017
Sana Hamilton Resume		2016
Gail Nankivell CV		3 June 2017
Melissa Lim CV		2017
Consent Form	V2	October 2017
Child Information Sheet	V3	November 2017
Dr. Deshpande Aniruddh Vijay CV brief		June 2017
Response to HREC		October 2017
Young Person Information Sheet	V2	October 2017
Email cover letter		21 November 2017

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

SGarnett

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

***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*. Please provide this office with a copy of your registration number for our records if you have not already done so.**