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

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11 September 2018

A/Prof Aaron Schindeler
Bioengineering and Molecular Medicine
The Children's Hospital at Westmead

Dear A/Prof Schindeler,

HREC Reference:	**HREC/18/SCHN/288**
Project title:	**A single centre, 12-week, single-arm trial to examine compliance, safety and efficacy of daily L-carnitine supplementation (1000mg) for the treatment of childhood Neurofibromatosis Type 1 (NF1)- associated muscle weakness and fatigue**
Sites:	**The Children's Hospital at Westmead**

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 July 2018** and subsequently by the Executive of SCHN HREC on the **10 September 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 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*
Child Behaviour Sample questionnaire electronic version		Received 2 July 2018
Child/Young person Information Sheet	V3.0	06 Sep 2018
HREA, Submission code: AU/1/CC8736		30 June 2018
Parent/Guardian Information Sheet	V3.0	06 Sep 2018
PedsQL-3.0-Neuromuscular-All (eng-AU)	V3.0	Received 2 July 2018
PedsQL-4.0-Core-All (eng-AU)	V4.0	Received 2 July 2018
Product Information (MUSASHI CARNITINE)		30 Nov 2016
Proof of Child Behaviour Checklist Questionnaire application		25 May 2018
Team member withdrawal email		26 May 2018
Consent Form – Parent/Guardian	V3.0	06 Sep 2018
Updated HREA form		31 Aug 2018
Letter from Stephen Alexander RE: Carnitine Dose		20 Aug 2018
NF1 carnitine trial cover letter Schindeler		31 Aug 2018
Protocol	V2.0	30 Aug 2018
Response to ethics committee		Received 31 Aug 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

Sarah Garnett

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

CC Emily Vasiljevski

***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.**