ETHICS APPROVAL & GOVERNANCE AUTHORISATION

4 August 2016

A/Prof Cathy Catroppa
Psychology
RCH

Dear A/Prof Catroppa

Project Title: A pilot intervention program for cognitive and social sequelae following acquired brain injury in childhood and adolescence.

RCH HREC Reference Number: 29099 J

I am pleased to advise that the below modification has received ethical approval from The Royal Children's Hospital Melbourne Human Research Ethics Committee (HREC).

The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHRMC) National Statement on Ethical Conduct in Human Research (2007), and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

The modification has also received governance authorisation at the Melbourne Children's Campus (incorporating The Royal Children's Hospital, Murdoch Children's Research Institute and the University of Melbourne Department of Paediatrics).

HREC Approval Date: 4 August 2016

Participating Sites:
Ethical approval for this project applies at the following sites:

Site Name
• The Royal Children's Hospital and Murdoch Childrens Research Institute

Approved Documents:
The following documents have been reviewed and approved:

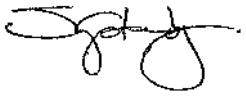
Document	**Version**	**Date**
Protocol	V7	July 2016
PGIS & CF	V6	July 2016
PIS & CF	V6	July 2016
Information Sheet (waitlist controls)	V1	June 2016
Telephone call script	version not provided	July 2016
Tracing letter	Version not provided	July 2016

Conditions of Ethics Approval:

- You are required to submit to the HREC:
  - An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics

approval is contingent on submission of an annual report, due within one month of the approval anniversary. Failure to comply with this requirement may result in suspension of the project by the HREC.
    - A comprehensive Final Report upon completion of the project.
- Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.
- Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement: *Monitoring and reporting of safety for clinical trials involving therapeutic products May 2009*.
- Notify the reviewing HREC of your inability to continue as Coordinating Principal Investigator.
- Notify the reviewing HREC of the failure to commence the study within 12 months of the HREC approval date or if a decision is taken to end the study at any of the sites prior to the expected date of completion.
- Notify the reviewing HREC of any matters which may impact the conduct of the project.
- If your project involves radiation, you are legally obliged to conduct your research in accordance with the Australian Radiation Protection and Nuclear Safety Agency Code of Practice 'Exposure of Humans to Ionizing Radiation for Research Purposes' Radiation Protection series Publication No.8 (May 2005)(ARPANSA Code).
- The HREC, authorising institution and/or their delegate/s may conduct an audit of the project at any time.

Yours sincerely



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