

Thursday, 29 November 2018

Ms Anna Seidler
NH&MRC Clinical Trials Centre; Faculty of Medicine and Health
Email: lene.seidler@sydney.edu.au

Dear Anna,

The University of Sydney Human Research Ethics Committee (HREC) has considered your application. I am pleased to inform you that after consideration of your response, your project has been approved.

Details of the approval are as follows:

Project No.:	2018/886
Project Title:	Systematic review and network meta-analysis with individual participant data on Cord Management at Preterm Birth (iCoMP)
Authorised Personnel:	Seidler Anna; Askie Lisa; Duley Lelia; Montgomery Alan;
Approval Period:	29/11/2018 – 29/11/2022
First Annual Report Due:	29/11/2019

Condition/s of Approval

- Research must be conducted according to the approved proposal.
- An annual progress report must be submitted to the Ethics Office on or before the anniversary of approval and on completion of the project.
- You must report as soon as practicable anything that might warrant review of ethical approval of the project including:
 - Serious or unexpected adverse events (which should be reported within 72 hours).
 - Unforeseen events that might affect continued ethical acceptability of the project.
- Any changes to the proposal must be approved prior to their implementation (except where an amendment is undertaken to eliminate *immediate* risk to participants).
- Personnel working on this project must be sufficiently qualified by education, training and experience for their role, or adequately supervised. Changes to personnel must be reported and approved.
- Personnel must disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, as relevant to this project.
- Data and primary materials must be retained and stored in accordance with the relevant legislation and University guidelines.
- Ethics approval is dependent upon ongoing compliance of the research with the *National Statement on Ethical Conduct in Human Research*, the *Australian Code for the Responsible Conduct of Research*, applicable legal requirements, and with University policies, procedures and governance requirements.
- The Ethics Office may conduct audits on approved projects.



- The Chief Investigator has ultimate responsibility for the conduct of the research and is responsible for ensuring all others involved will conduct the research in accordance with the above.

This letter constitutes ethical approval only.

Please contact the Ethics Office should you require further information or clarification.

Sincerely,

Associate Professor Michael Skilton
Chair, Health Review Committee (Low Risk)

The University of Sydney of Sydney HRECs are constituted and operate in accordance with the National Health and Medical Research Council's (NHMRC) [National Statement on Ethical Conduct in Human Research \(2007\)](#) and the NHMRC's [Australian Code for the Responsible Conduct of Research \(2007\)](#)