MonashHealth

Research Directorate
Monash Health
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Tel (03) 9594 4611
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18 September 2013

Professor David Story
Anaesthesia Department
Melbourne Medical School
The University of Melbourne
Parkville Vic 3050

Dear Researcher,

SERP Ref: HREC/13/SHB/28

Research Project Application No. 13267B: Association Between Maternal Size and Outcomes for Caesarean Section: A Multicentre Prospective Observational Study (The MUM SIZE Study)

The Monash Health HREC B reviewed the above application at the meeting held on 22 August 2013 In addition, the HREC is satisfied that the responses to our correspondence of 23 August 2013 have been sufficiently addressed.

The HREC approved the above application on the basis of the information provided in the application form, protocol and supporting documentation.

This reviewing HREC is accredited by the Consultative Council for Clinical Trial Research under the single ethical review system.

Approval

The HREC approval is from 18 September 2013.

Approval is given in accordance with the research conforming to the *National Health and Medical Research Council Act 1992* and the *National Statement on Ethical Conduct in Human Research (2007)*. The HREC has ethically approved this research according to the Memorandum of Understanding between the Consultative Council and the participating organisations conducting the research.

Approval is given for this research project to be conducted at the following sites and campuses:

- Western Hospital
- The Royal Women's Hospital
- Northern Hospital
- Ballarat Base Hospital
- Shepparton Regional Hospital
- Sunshine Hospital

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You must comply with the following conditions:

The Chief Principal Investigator is required to notify the Manager, Human Research Ethics Committees, Monash Health of:

1. Any change in protocol and the reason for that change together with an indication of ethical implications (if any)
2. Serious or unexpected adverse effects of project on subjects and steps taken to deal with them
3. Any unforeseen events that might affect continued ethical acceptability of the project
4. Any expiry of the insurance coverage provided in respect of sponsored trials
5. Discontinuation of the project before the expected date of completion, giving reasons
6. Any change in personnel involved in the research project including any study member resigning from Monash Health &/or the study team.

At the conclusion of the project or every twelve months if the project continues, the Principal Investigator is required to complete and forward an annual progress report to the Committee.

Reminders to submit annual progress report forms will be forwarded to the researcher.

The Coordinating Principal Investigator is responsible for notifying Principal Investigators. The Coordinating Principal Investigator and Principal Investigators should forward a copy of this letter to their site's Research Governance Officer.

Approved documents

Documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Protocol Number APPMU001	1.5	16 September 2013
National Ethics Application Form		16 September 2013
MUM SIZE Study CRF (including Verbal Consent Form)		
Victorian Specific Module		16 September 2013

Site-Specific Assessment (SSA)

SSA authorisation is required at all sites participating in the study. SSA must be authorised at a site before the research project can commence.

The completed Site-Specific Assessment Form and a copy of this ethics approval letter must be submitted to the Research Governance Officer for authorisation by the Chief Executive or delegate. This applies to each site participating in the research.

If you should have any queries about your project please contact Deborah Dell or Julie Gephart by email deborah.dell@southernhealth.org.au /julie.gephart@southernhealth.org.au

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The HREC wishes you and your colleagues every success in your research.

Yours sincerely

Dr Simon Bower
Chair, HREC B

Checklist: Post-ethics approval requirements that must be met before a research project can commence at a study site.

Please ensure that as a PI (including the CPI) the following are completed at each study site.

Requirements	**Yes/No/NA**
Ethics approval notification The PI must send a copy to the RGO at that study site.	Yes
HREC Review Only Indemnity The PI must forward a copy of the signed HREC Review Only Indemnity to the RGO at that study site.	N/A
CTN notification The PI must sign the CTN and forward to the RGO so the authority approving the conduct of the trial, at that site, can complete and sign.	N/A
SSA authorisation notification The PI must forward the SSA form and attached documents (e.g. CTRA) to the RGO so the authority approving the conduct of the trial, at that site, can complete and sign.	Yes
Radiation If applicable, the RGO must contact the Medical Physicist to notify DHS, Radiation Safety Section to list the project on the Institute's licence.	N/A
Other Commonwealth statutory requirements Ensure compliance with the following e.g. Office of the Gene Technology Regulator, NHMRC Licensing Committee, NHMRC Cellular Therapies Advisory Committee.	N/A