

Metro North

Hospital and Health Service

Royal Brisbane & Women's Hospital Human Research Ethics Committee

Enquiries to:

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HREC/15/QRBW/108

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Dr Alex Mowat 17 Illidge Street

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Dear Dr Mowat,

Re: Ref N^{o} : HREC/15/QRBW/108: Learning curve for Laparoscopic Sacrocolpopexy in a Brisbane setting

In my capacity as Chairperson of a National Health and Medical Research Council (NHMRC) registered Human Research Ethics Committee, I reviewed the above project on 06 March 2015 to provide an opinion on whether this project is exempt from HREC review.

I believe that this project does not meet the NHMRC "National Statement on Ethical Conduct in Human Research" 2007 definition of research and is compliant with the NHMRC guidance "Ethical Considerations in Quality Assurance and Evaluation Activities" 2014. As such, I recommend that HREC review is not required.

The above guidance recommends that there should be appropriate oversight of quality assurance (QA) and evaluation activities. Therefore the Safety and Quality Unit at RBWH will be informed about this work, and should also be notified by you:

- If the project has not commenced within 3 months.
- Of the outcome, in the form of a report, within three months of completion.

Should there be a change to the scope or nature of the project which might affect this opinion, or an amendment to the project, please contact the Safety and Quality Unit (RBWH_QA@health.qld.gov.au phone 3646 1546) who may need to consult with the HREC Chairperson. The above NHMRC guidance details potential triggers for such reconsideration of ethical review.

I would like to offer you every success for the outcome of the project.

Should you have any queries about this letter please contact the Research Ethics Office on 07 3646 5490.

Yours sincerely,

Dr Conor Brophy

Chairperson RBWH Human Research Ethics Committee

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06.03.2015