



3 August 2015

Assoc Prof Judy Magarey
School of Nursing
The University of Adelaide
ADELAIDE SA 5005

Dear Assoc Prof Magarey,

HREC reference number: HREC/13/TQEHLMH/226

Project title: A Mother's heart beats for two: to explore the current provision of evidence based practice, outcomes and 'Lived experience' for women with cardiovascular disease during pregnancy.

RE: Ethics Application – Extension of Approval

Thank you for your request for an extension to the approval for the above project.

I am pleased to advise that your protocol is granted further extended approval, and meets the requirements of the *National Statement on Ethical Conduct in Human Research, incorporating all updates*. The documents previously reviewed and approved include:

Document	Version	Date
Application: LNR Proposal		3 September 2013
Clinical Medical Case Note Audit Tool, including Appendices	Unknown	undated

Sites covered by this approval:

- **Lyell McEwin Hospital, SA**
- **Women's & Children's Hospital, SA**
- **Flinders Medical Centre, SA**

HREC approval is valid from **27 November 2014 to 27 November 2017**.

Please note that approvals are subject to annual review reports submitted every 12 months from the date of approval. Failure to submit reports may result in the HREC revoking its approval. The responsibility of submitting an annual review reporting is with the Coordinating Principal investigator.

Please note the following continued conditions of approval:

1. This HREC is the South Australian 'lead HREC' for the purpose of this ethics approval. Any study sites that are not listed on this letter are not covered by this ethics approval. Any SA study-sites within the public health system that wish to be added must contact the CPI, who must write formally to this HREC requesting the additional study site and a separate formal letter will be issued.
2. Annual review reports must be submitted to the HREC, every 12-months from the date of approval. Each site covered by this HREC must submit a report, and it is the responsibility of the Coordinating Principal investigator to ensure this is carried out.
3. Researchers are required to immediately report to this HREC anything which might warrant review of ethical approval of the study, including:
 - a. serious or unexpected adverse effects on participants;
 - b. proposed changes in the study; and
 - c. unforeseen events that might affect continued ethical acceptability of the project.
4. Confidentiality of the research subjects shall be maintained at all times as required by law.
5. All research subjects shall be provided with a Participant Information Sheet and Consent Form, unless otherwise approved by the HREC.



6. Adequate record-keeping must be maintained in accordance with GCP, NHMRC and state and national guidelines. The duration of record retention for all clinical research data is 15 years from the date of publication.
7. SA Health requires all institutions under its jurisdiction to dispose of research materials in accordance with the requirements outlined in the NHMRC Australian Code for the Responsible Conduct of Research.
8. A report and a copy of any published material should be forwarded to the HREC at the completion of the project.

This Committee is constituted in accordance with the NHMRC *National Statement on the Ethical Conduct of Human Research (2007)* and incorporating all updates.

Should you have any queries about the HREC's consideration of your project please the HREC Executive Officer on 08 8222 6841 or qeh.ethics@health.sa.gov.au

Yours sincerely

A handwritten signature in blue ink, appearing to read 'H O'Dea'.

Mrs Heather O'Dea
Team Leader, Executive Officer
Human Research Ethics Committee (TQEH/LMH/MH)