

Women and Newborn Health Service Ethics Committee 374 Bagot Road SUBIACO WA 6008

14 June 2017

Dr Sharon Perrella M310, 33 Stirling Highway Nedlands Western Australia 6009

Dear Dr Perrella

PRN:

RGS0000000103

Project Title:

Exploring changes in breastmilk composition as markers of mastitis in

mothers of preterm infants

Protocol No:

RGS0000000103

Thank you for submitting the above research project for ethical review. This project was considered by the Women and Newborn Health Service Ethics Committee at its meeting held on 24 May 2017.

I am pleased to advise you that the Women and Newborn Health Service Ethics Committee has granted ethical approval of this research project.

The nominated participating site(s) in this project is/are:

King Edward Memorial Hospital

[Note: If additional sites are recruited prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the Human Research Ethics Committee (HREC). Notification of withdrawn sites should also be provided to the HREC in a timely fashion.]

The approved documents include:

Document	Version	Version Date
Appendix1_Background Questionnaire	1.00	02/02/2017
Appendix2_Breast Health Questionnaire	1.00	02/02/2017
Appendix3_Sample Instructions	1.00	02/02/2017
Appendix4_Case Report Form	1.00	02/02/2017
Appendix5_Feedback Interview	1.00	02/02/2017
Appendix6_FU Questionnaire	1.00	02/02/2017
Consent Form	1.00	02/02/2017
Operating ProceduresNaK_POC_MeasurementDevices	1.00	28/03/2017

Protocol	3.00	11/05/2017
Participant Information	2.00	11/05/2017

Ethical approval of this project from Women and Newborn Health Service Ethics Committee is valid from 24 May 2017 to 25 May 2020 subject to compliance with the 'Conditions of Ethics Approval for a Research Project' (Appendix A).

The following project specific conditions must also be met:

A copy of this ethical approval letter must be submitted by all site Principal Investigators to the Research Governance Office or equivalent body or individual at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site/s.

<u>This letter constitutes ethical approval only.</u> This project cannot proceed at any site until separate site authorisation has been obtained from the Chief Executive or Delegate of the site under whose auspices the research will be conducted at that site.

Should you have any queries about the Women and Newborn Health Service Ethics Committee's consideration of your project, please contact the Ethics Office at kemhethics@health.wa.gov.au or on 08 6458 1667. The HREC's Terms of Reference, Standard Operating Procedures and membership are available from the Ethics Office or from http://www.kemh.health.wa.gov.au/development/resources/ethics.htm.

The HREC wishes you every success in your research.

Yours sincerely

Dr Allison Johns

Acting Executive Director Medical Services

Women and Newborn Health Services