26th October 2018

Women's & Children's Hospital

Research Secretariat
Level 2, Samuel Way Building
72 King William Road
North Adelaide SA 5006
Tel 08 8161 6390
Tel 08 8161 6521
www.wch.sa.gov.au

Prof G Dekker
Department of Obstetrics & Gynaecology
Lyell McEwin Hospital

Dear Prof Dekker

Re: Prediction and Prevention of Preeclampsia. HREC/18/WCHN/73. Ethics expiry date: 31/10/2021.

Lead HREC for the above study for the following institutions/sites:

Lyell McEwin Hospital

Thank you for your emails dated 9th July 2018, 30th August 2018, 6th September 2018, 24th September 2018, 24th October 2018 and 25th October 2018 in response to matters raised following the expedited review of the above Low and Negligible Risk application by the Chair and two members of the WCHN HREC. I am pleased to advise that the application has been granted full ethics approval and meets the requirements of the *National Statement on Ethical Conduct in Human Research.*

Specifically, the following documents have been noted/approved:

Document	*Version*	*Date*
Protocol		22 May 2018
HREA Application: AU/1/7796320		24 May 2018
Participant Information & Consent Form	5	24 October 2018

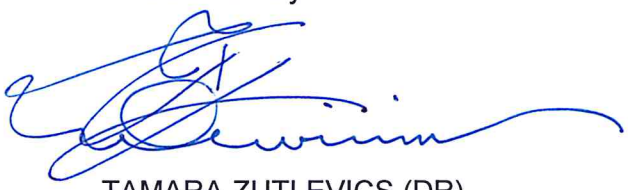
This letter constitutes advice on ethical consideration only. You must not commence this research project at a site until you have obtained separate research governance approval from the site concerned. A copy of this letter should be forwarded to all site investigators for submission to the relevant Research Governance Officer.

At the WCHN, or any other SA Health site, separate authorisation from the Chief Executive or delegate of that site must be obtained through a Site Specific Assessment (SSA) request. For information on this process at the WCHN, please contact the WCHN Research Governance Officer, Ms Camilla Liddy (telephone 8161 6688, email camilla.liddy@health.sa.gov.au).

I remind you approval is given subject to:
- immediate notification of any serious or unexpected adverse events to participants;
- immediate notification of any unforeseen events that might affect continued ethical acceptability of the project;
- submission of any proposed changes to the original protocol. Changes must be approved by the Committee before they are implemented;
- immediate advice, giving reasons, if the protocol is discontinued before its completion;
- submission of an annual report on the progress of the study, and a final report when it is completed to the WCHN Research Governance Officer. It is your responsibility to provide these reports, without reminder. The proforma for the report may be found on the WCHN Research Governance and Ethics website.

Approval is given for three years only. If the study is more prolonged than this, an extension request should be submitted unless there are significant modifications, in which case a new submission may be required. Please note the expiry date in the title above and include it in any future communications.

Yours sincerely



TAMARA ZUTLEVICS (DR)
CHAIR
WCHN HUMAN RESEARCH ETHICS COMMITTEE