



HUMAN RESEARCH ETHICS COMMITTEE

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25 October 2018

Dr Amanda Henry
Department of Women's and Children's Health
Level 2 Prichard Wing
St George Hospital
KOGARAH NSW 2217

Dear Dr Henry,

HREC ref no: 18/193 (HREC/18/POWH/401)

Project title: BP2 (Blood Pressure Postpartum) study: a 3-arm, randomised trial of follow-up and lifestyle behaviour change strategies in the first 12 months after hypertensive pregnancy

Thank you for submitting the above application for ethical and scientific review. The application was first considered by the South Eastern Sydney Local Health District Human Research Ethics Committee (HREC) at a meeting on **28 August 2018**.

Your recent correspondence was reviewed at the HREC Executive Committee meeting on **24 October 2018**.

I am pleased to advise that that the proposal meets the requirements of the National Statement on Ethical Conduct of Human Research.

Ethics approval is granted for the following documents:

- HREA submission code AU/1/1D4837, dated 17 August 2018
- Distress Protocol V1 dated September 2018
- Study Protocol V2 dated September 2018
- PISCF V2 dated September 2018
- Patient Reported Experience 12 months postpartum V1 dated August 2018
- 6 month infant feeding questionnaire V1 dated August 2018
- Participant Invitation Letter V1 dated August 2018
- Infant feeding questionnaire 12 months postpartum V1 dated August 2018
- 6 month postpartum questionnaire V1 dated August 2018

Ethics approval is granted for the following site(s):

- St George Public Hospital



- Royal Prince Alfred Hospital
- Liverpool Hospital
- Campbelltown Hospital
- Royal Hospital for Women

Conditions of approval

1. This approval is valid for 5 years from the date of this letter.
2. Annual reports must be provided on the anniversary of approval.
3. A final report must be provided at the completion of the project.
4. Proposed changes to the research protocol, conduct of the research, or length of approval will be provided to the Committee.
5. The Principal Investigator will immediately report matters which might warrant review of ethical approval, including unforeseen events which might affect the ethical acceptability of the project and any complaints made by study participants.

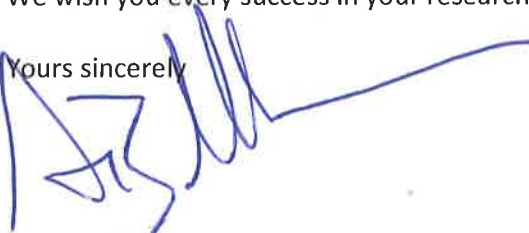
For Public Health Sites Only: You are reminded that this letter constitutes ethical approval only. You must not commence this research project until you have submitted your Site Specific Assessment (SSA) to the Research Governance Officer of the appropriate institution and have received a letter of authorisation from the General Manager or Chief Executive of that institution.

Should you have any queries, please contact the Research Support Office on (02) 9382 3587. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Research Support Office website:
<https://www.seslhd.health.nsw.gov.au/services-clinics/directory/seslhd-research>

Please quote **18/193** in all correspondence.

We wish you every success in your research.

Yours sincerely



Andrew Bohlken

Executive Officer, Human Research Ethics Committee

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*, NHMRC and Universities Australia *Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.