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To: angela.makris@health.nsw.gov.au
Cc: angela.makris@health.nsw.gov.au; swslhd-ethics@health.nsw.gov.au
Subject: 2020/ETH02171: Application HREA - Approved

Date of Decision Notification: **16 Dec 2020**

Dear Adjunct Professor Angela Makris,

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

2020/ETH02171: Self – created records by eAPP for early antenatal hospital access

This Application was reviewed as a **Greater than low risk review pathway** and was initially considered by the **South Western Sydney Local Health District Human Research Ethics Committee**.

The project was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED**.

****THIS EMAIL CONSTITUTES ETHICAL APPROVAL ONLY – SITE SPECIFIC APPLICATION IS REQUIRED BEFORE ANY RESEARCH CAN COMMENCE AT ANY NSW PUBLIC HEALTH SITE****

This project cannot proceed at any site until separate research governance authorisation has been obtained from the Institution at which the research will take place.

This project has been ethically approved to be conducted at the following sites: - **Please ensure site specific applications are submitted and authorised prior to any research commencing at the below sites:**

- **Liverpool Hospital**
- **Bankstown Lidcombe Hospital**
- **Campbelltown Hospital**
- **Fairfield Hospital**

The following documentation was reviewed and is included in this approval:

- Human Research Ethics Application, Version 6.0, 11.12.2020
- Protocol, Version 2.0, 02.11.2020
- MASTER Participant Information Sheet, Version 2.0, 02.11.2020
- Appendix A: Screen App Questionnaire, Version 2.0, 02.11.2020
- Midwife – Patient Interaction Questionnaire, Version N/A

[Application Documents](#) - (link will only be active for 14 days from the decision date. The approved documents are also available to download from forms section of this project in REGIS)

The Human Research Ethics Application reviewed by the HREC was:
Version: 1.05
Date: 11 Dec 2020

The approval is for a period of 5 years from the date of this e-mail (**16 Dec 2020**)

The Coordinating Principal Investigator will:

- provide the HREC with an annual report and the final report when the project is completed at all sites. This will be through the submission of a milestone in REGIS.
- immediately report anything that might warrant review of ethical approval of the project.
- submit proposed amendments to the research protocol, including; the general conduct of the research, changes to CPI or site PI, an extension to HREC approval, or the addition of sites to the HREC before those changes can take effect. This will be through a notification of an amendment in REGIS
- will notify the HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.

Submission of annual progress/final reports (milestone), amendments and safety reports should be done through the forms provided in REGIS. Guidance on these processes can be found on the [REGIS website](#).

It is noted that the **South Western Sydney Local Health District Human Research Ethics Committee** is constituted in accordance with the National Statement on Human Conduct in Research, 2007 (NHMRC).

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below. We look forward to managing this study with you throughout the project lifecycle.

Please note the following conditions of approval:

****Condition of approval: Please ensure that the restrictions and social distancing for COVID-19 are followed until the restrictions have been lifted****

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including: any serious or unexpected adverse events; and unforeseen events that might affect continued ethical acceptability of the project.
1. The Principal Investigator will report proposed changes to the research protocol, conduct of the research, or length of HREC approval to the HREC in the specified format, for review. For multi-centre studies, the Chief Investigator should submit to the Lead HREC and then send the amendment approval letter to the investigators at each sites so that they can notify their Research Governance Officer.
1. The Principal Investigator will inform the HREC, giving reasons, if the project is discontinued before the expected date of completion.
1. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.
1. The Principal Investigator must reassure participants about confidentiality of the data.
1. Proposed changes to the personnel involved in the study are submitted to the HREC accompanied by a CV where applicable.
1. The Principal Investigator is responsible for ensuring the research project is conducted in line with relevant NSW Health, South Western Sydney Local Health

District and Hospital policies available from:
<https://www.swslhd.health.nsw.gov.au/ethics/policies.html>

Should you have any queries about your project please contact **Andrea Lee** on the telephone number 8738 8304. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the SWSLHD website:
<https://www.swslhd.health.nsw.gov.au/ethics/>

Please quote the Local HREC reference **2020/ETH02171** in all correspondence. The HREC wishes you every success in your research.

Yours faithfully

Mrs Andrea Kennedy

on behalf of

A/Professor Murray Killingsworth

Chairperson, SWSLHD 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)*. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

SWSLHD Research Directorate Christmas Closure:

-Closing submission date for greater than low risk ethics applications – 27.11.2020

-Closing submission date for Low risk ethics applications – 04.12.2020

-Closing submission date for Site specific applications – 04.12.2020

The Research Ethics and Governance Office will be closed for all submissions from the 18.12.2020 – reopening on the 11.01.2021

We wish you a safe and happy holiday period and look forward to working with you in 2021.

Kind regards,

Andrea Kennedy

A/Research Ethics and Governance Manager | **Research Directorate**

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<https://www.swslhd.health.nsw.gov.au/ethics/>

Use REGIS for all Research Applications

The Research and Ethics Office is using [REGIS](#) for all Research Applications (HREA and SSA).

Research Webinars!

The Research Directorate is holding webinars on the first and third Wednesday of each month at 2pm via Skype from February onwards. The webinars cover REGIS and research application information for SWSLHD. For more information on how to attend the webinars and view material for previous webinars, please click

<https://www.swslhd.health.nsw.gov.au/ethics/training.html>