The Royal Melbourne Hospital

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Ethical Approval

Royal Melbourne Hospital Human Research Ethics Committee

A/Prof Joanne Said
Sunshine Hospital
ST ALBANS 3021

28 October 2022

Dear A/Prof Joanne Said,

HREC Reference Number: HREC/85882/MH-2022
Royal Melbourne Hospital Site Reference Number: 2022.123
Project Title: PRECeDe Trial: Prevention of neonatal Respiratory distress with antenatal corticosteroids prior to Elective Caesarean section in women with diabetes – A Randomised Trial

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I am pleased to advise that the above project has **received ethical approval** from the Royal Melbourne Hospital Human Research Ethics Committee (HREC). The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHRMC) National Statement on Ethical Conduct in Human Research (2007), and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

HREC Approval Date: 27 October 2022

Ethical approval for this project applies at the following sites:

Site
• Western Health - Sunshine Hospital
• Monash Medical Centre
• The Royal Womens Hospital
• St George Hospital
• Mercy Hospital for Women
• Royal Brisbane and Womens Hospital
• The Royal Hospital for Women
• Mater Mothers Hospital
• Women and Childrens Hospital
• Fiona Stanley Hospital

Approved Documents:

The following documents have been reviewed and approved:

Document	Version	Date
Protocol	3.0	06 October 2022
Master Main Participant Information Sheet/Consent Form	3.0	06 October 2022

CRF 0: Patient Screening and Eligibility Confirmation	1.0	02 May 2022
CRF 1: Consent and Randomisation	1.0	02 May 2022
CRF 2: Contact Details	1.0	02 May 2022
CRF 3: Baseline Data	1.0	02 May 2022
CRF 4: Drug Administration	1.0	02 May 2022
CRF 5: Maternal Delivery Data	1.0	02 May 2022
CRF 6: Baby Birth Data	1.0	02 May 2022
CRF 7: Baby Nursery Admission and RDS data	1.0	02 May 2022
CRF 8: Follow up and Outcome	1.0	02 May 2022
CRF 9: Adverse Event	1.0	02 May 2022
CRF 10: Serious Adverse Event Reporting	2.0	12 August 2022
CRF 11: Protocol Deviation	1.0	02 May 2022
CRF 12: Withdrawal of Consent	1.0	02 May 2022
PRECeDe Banners	1.0	11 May 2022
PRECeDe Flyers	1.0	11 May 2022
PRECeDe Patient Alert Cards	1.0	11 May 2022
PRECeDe Poster	1.0	11 May 2022
Master Blood Sugar Diary	1.0	11 May 2022
SF12 Patient Questionnaire	2.0	-
Participant Instructions Following Injections	2.0	08 August 2022
Postpartum Questionnaire	1.0	08 August 2022
Symptoms Questionnaire	1.0	11 May 2022
Caesarean Section Not in Labour – Weekly Screening Log	1.0	11 May 2022

Noted Document	**Version**	**Date**
Data Monitoring Committee Terms of Reference	1.0	22 August 2022
Safety Monitoring Committee Terms of Reference	1.0	22 August 2022
Investigator's Brochure (Celestone Chronodose)	-	24 February 2022
WASM	1.0	27 June 2022

Governance Authorisation:

Governance Authorisation is required at each site participating in the study before the research project can commence at that site.

You are required to provide a copy of this HREC approval letter to the principal investigator for each site covered by this ethics approval for inclusion in the site specific assessment application.

Conditions of Ethics Approval:

- You are required to submit to the HREC:
    - An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due by 31 March each year. Continuation of ethics approval is contingent on submission of an annual report being submitted by 31 March each year. Failure to comply with this requirement may result in suspension/withdrawal of the project by the HREC.
    - A comprehensive Final Report upon completion of the project.

- Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.
- Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC's Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016) guideline.
- Notify the reviewing HREC of your inability to continue as Coordinating Principal Investigator.
- Notify the reviewing HREC of the failure to commence the study within 12 months of the HREC approval date or if a decision is taken to end the study at any of the sites prior to the expected date of completion.
- Notify the reviewing HREC of any matters which may impact the conduct of the project.
- If your project involves radiation, you are legally obliged to conduct your research in accordance with the Australian Radiation Protection and Nuclear Safety Agency Code of Practice 'Exposure of Humans to Ionizing Radiation for Research Purposes' Radiation Protection series Publication No.8 (May 2005)(ARPANSA Code).

Please note: Template forms for reporting Amendments, safety reporting, Annual/Final reports, etc. can be accessed from: https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting

NSW sites:

If your trial includes participants in NSW who may be incapable of providing valid consent to participate for themselves, the HREC suggest that you make yourself aware of the provisions of the *Medical Treatment Planning and Decisions Act 2016.* Prior to commencing your trial in NSW, you may need to make an application to the NSW Civil and Administrative Tribunal (NCAT) for approval for your trial to proceed as well as to provide direction on the appropriate consent mechanism. Please note that the Act contains serious penalties for conducting clinical trial research on non-competent participants without proper authorisation.

The HREC may conduct an audit of the project at any time.

Yours sincerely,

Prof Peter Colman
Chair – Royal Melbourne Hospital Human Research Ethics Committee (HREC)