

Enquiries to: Metro North HREC  
Telephone: 07 3646 5280  
Email: [MetroNorthResearch-Ethics@health.qld.gov.au](mailto:MetroNorthResearch-Ethics@health.qld.gov.au)  
File Ref: ERM: 105360 Approval

Metro North Health

28 May 2024

Dr Rachael Nugent  
Sunshine Coast Hospital and Health Service  
E: [rachael.nugent@health.qld.gov.au](mailto:rachael.nugent@health.qld.gov.au)  
Cc: [lauren.kearney@uq.edu.au](mailto:lauren.kearney@uq.edu.au) [lauren.kearney@health.qld.gov.au](mailto:lauren.kearney@health.qld.gov.au)

Dear Dr Rachael Nugent

**Re: Project ID: 105360; HREC/2024/MNHA/105360; OPTIMISING induction of labour care: oral misoprostol versus balloon dilatation within a stratified inpatient to outpatient setting [The OptiMis-IO study]**

Thank you for submitting the above research project for ethical review. This project was considered by the Metro North Health Human Research Ethics Committee (HREC) A (EC 00172) at its meeting held on 19 March 2024.

I am pleased to advise that this research project meets the requirements of the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2023)* and that the HREC granted final ethical approval of this research project.

**Note:** If additional sites are engaged prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the HREC. Notification of withdrawn sites should also be provided to the HREC in a timely fashion.

**This letter constitutes ethical approval only.** This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site.

The reviewed and approved documents include:

<b>Document</b>	<b>Version</b>	<b>Date</b>
Form Reference: HREA	Feb ver 2	09 February 2024
Australian Product Information – Angusta (Misoprostol)	-	20 December 2022
Therapeutic Goods Administration - ANGUSTA misoprostol 25 microgram tablet blister pack		14 March 2023
2023 Collaborative Research Grant Conditions of Award (noted)	-	04 January 2024
Data Collection Instrument - RedCap	1	31 January 2024
Curriculum Vitae – Dr Jane Maher	-	07 February 2023
GCP – Dr Jane Maher	-	10 January 2024
Curriculum Viata- Dr Rebecca Jenkinson	-	17 August 2023
GCP – Dr Rebecca Jenkinson	-	11 January 2024
Response to further information requested - Form Reference: HREA	May ver 3	3 May 2024

Letter	-	3 May 2024
Response Letter	-	30 April 2024
CV – Dr Rachael Nugent	-	-
CGP - Dr Rachael Nugent	-	17 August 2022
Phone Script	1	30 April 2024
Protocol	2	30 April 2024
Maternal Questionnaire	2	1 May 2024
Staff Focus Group Interview Guide	1	31 January 2024
Response to further information requested - Form Reference: HREA	May ver 4	24 May 2024
Response letter	-	24 May 2024
Master Participant Information Sheet/Consent Form – Study 1	3	24 May 2024
Master Participant Information Sheet/Consent Form – Study 2	3	24 May 2024
Master Invitation to Participate - Staff Focus Group – Study 1	3	24 May 2024

This information will be tabled for noting at the next HREC meeting to be held on 18 June 2024.

Ongoing approval is for the duration of the project, conditional on:

1. In accordance with Section 5.5.6 (b) of the National Statement the Principal Investigator will report to the HREC annually (**Due by 30 April each year**) in the specified format and a final report is to be submitted on completion of the study.  
[www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp](http://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp)
2. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
  - a. Unforeseen events that might affect continued ethical acceptability of the project.
  - b. Serious Adverse Events that materially impact on the continued ethical acceptability of the project.
3. Amendments to the research project are to be submitted to the HREC for review. Amendments should be reflected in a cover letter from the principal investigator, providing a description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study. Further advice on submitting amendments is available from:  
[www.health.qld.gov.au/metronorth.health.qld.gov.au/research/ethics-and-governance/post-approval-reporting](http://www.health.qld.gov.au/metronorth.health.qld.gov.au/research/ethics-and-governance/post-approval-reporting)
4. The Principal Investigator will notify the HREC if the project is discontinued at the participating site(s), with reasons provided.
5. If additional sites are engaged prior to the commencement of, or during the research project, the Principal Investigator is required to notify the HREC. Notification of the withdrawn sites should also be provided to the HREC in a timely fashion accompanying a close out report for that site.

- Please advise the HREC of the date you commence the research project for the approved site(s) using the Notification of Commencement Form:  
[www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp](http://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp)
- The HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from: [https://www.health.qld.gov.au/hiiro/html/regu/regu\\_home](https://www.health.qld.gov.au/hiiro/html/regu/regu_home)

The nominated participating sites for this project are:

No.	Site
1.	Sunshine Coast University Hospital
2.	Royal Brisbane Women's Hospital

The Metro North Health HREC wishes you every success in your research.

Yours sincerely,


 Digitally signed  
 by Dr Sarah  
 Winch  
 Date: 2024.05.28  
 12:01:59 +10'00'

**Dr Sarah Winch**  
**Chairperson, Metro North Health Human Research Ethics Committee A (EC 00172)**  
 Metro North Office of Research  
 Metro North Health

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.