Office for Research
The Royal Melbourne Hospital
Level 2 South West
300 Grattan Street
Parkville VIC 3050
Australia

Telephone: +61 3 9342 8530
Facsimile: +61 3 9342 8548
Email: research@mh.org.au
thermh.org.au
ABN 73 802 706 972

Ethical Approval

Royal Melbourne Hospital Human Research Ethics Committee

A/Prof Joanne Said
Sunshine Hospital
Maternal Fetal Medicine
Sunshine Hospital
176 Furlong Rd
3021, AUSTRALIA

21 December 2023

Dear A/Prof Joanne Said,

HREC Reference Number: HREC/92838/MH-2023
Royal Melbourne Hospital Site Reference Number: 2023.249
Project Title: ASAPP Pilot Trial: Azithromycin for Short cervix and Amniotic fluid sludge for the Prevention of Preterm birth

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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 (2023). 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 (2023), 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: 20 December 2023

Ethical approval for this project applies at the following sites:

Site
• Western Health • The Royal Women's Hospital • Monash Health • Eastern Health

Approved Documents:

The following documents have been reviewed and approved:

Document	Version	Date
Protocol	1.1	28 November 2023

Master Main Participant Information Sheet and Consent Form	1.1	28 November 2023
AASAP Trial Dosing Instructions	1.0	22 September 2023
AASAP Subject Trial Subject File Source Document	1.0	20 September 2023
AASAP Master Participant Alert Card	1.0	22 September 22023
AASAP Master Participant Flyer	1.0	19 October 2023

Noted Document	Version	Date
Australian Product Information - *Azithromycin dihydrate*	pfpzithb10623	19 June 2023

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 will be subject of a regulatory inspection, please notify the HREC of the proposed date of inspection.
- 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://www.thermh.org.au/research/office-for-research/post-approval-project-management

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)