



Mater Misericordiae Ltd
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6 December 2021

Dr Amanda Wee

Mater Pelvic Health Research and Education Unit
Mater Pimlico, Townsville, QLD 4812

Dear Dr Wee

Project Id: 75934

Project Title: Post-Operative Pessary In native Tissue repair (POP IT) a prospective RCT.

Full Project Title:

Reference Number: HREC/MML/75934 (V4)

Thank you for submitting the above research project for single ethical review. This project was considered by the Mater Misericordiae Ltd Human Research Ethics Committee (EC00332) (MML HREC) at its meeting held on 18 May 2021 and I further reviewed on 30 November 2021.

I am pleased to advise you that the above research project meets the requirements of the [National Statement on Ethical Conduct in Human Research \(2007\) updated 2018](#) and ethical approval for this research project has been granted by the Mater Misericordiae Ltd Human Research Ethics Committee (EC00332).

The nominated participating site for this project is:

- Mater Misericordiae Ltd (Mater Pimlico Hospital)

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 MML HREC. Notification of withdrawn sites should also be provided to the MML HREC in a timely fashion.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. At Mater Misericordiae Ltd please contact the Research Governance Office on 07 3163 3769.

The approved documents include:

Submission Document Name	Version	Date
Pre operative questionnaire	1	25-Aug-2021
Post operative questionnaire	1	25-Aug-2021
Response Letter (Noted)	1	27-Sep-2021
Protocol	4	28-Nov-2021
Participant information and consent form	4	28-Nov-2021
Cover Letter (Noted)	-	-
CV Awee (Noted)	-	-
CV Dhivya Thangavel (Noted)	-	-
CV-RANE (Noted)	-	-

Approval of this project by the MML HREC is valid from **6 December 2021 to 6 December 2024**, subject to the following conditions being met:

- The Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Principal Investigator will notify the MML HREC of any modification that is to be made to the protocol or other project documents and will submit any required amendments.

- The Principal Investigator will submit any necessary reports related to the safety of research participants.
- In accordance with *Section 5.5.5 (a)* of the National Statement, the Principal Investigator will report to the MML HREC annually, the first report to be submitted by **6 December2022** and a final report submitted on completion of the study with presentation or publication of the main findings.
- The Principal Investigator will notify the MML HREC if the project is discontinued before the expected completion date, with reasons provided.
- The Principal Investigator will notify the MML HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation.
- A copy of this approval letter together with completed Site Specific Assessment (SSA) and any other required documents must be submitted by all site Principal Investigators to the Research Governance Office at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site.

Please confirm the commencement date with the Research Ethics office.

Should you have any queries about the MML HREC's consideration of your project, please contact the HREC Liaison Officer on (07) 3163 1585. The MML HREC Terms of Reference, membership and standard forms are available from our [website](#).

The MML HREC wishes you every success in your research.

Yours sincerely



Professor Ross Pinkerton MD; FRCPCH

Chairperson

Mater Misericordiae Ltd Human Research Ethics Committee (EC00332)

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), updated 2015. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

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