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22 April 2022

Dr Lore Schierlitz
Mercy Hospital for Women
163 Studley Road
Heidelberg VIC 3084

Dear Dr Schierlitz,

Re 2022-005: A prospective cohort study for success of vaginal hysterectomy with vault suspension compared to Manchester-Fothergill Procedure for utero-vaginal prolapse

I am pleased to advise that the Mercy Health Human Research Ethics Committee has reviewed your documents and approved the above research, at its meeting on 12 April 2022.

The research has been approved as **more than low risk** research.

Approval

Approval is given in accordance with the research conforming to the *National Statement on Ethical Conduct in Human Research 2007 (updated 2018)*.

The **more than low risk** research is approval from **26 April 2022** until **15 March 2027**.

The research project is approved to be conducted at the following site:

- **Mercy Hospital for Women**

Approved documents - the following documents were reviewed and approved:

<u>Document</u>	<u>Version</u>	<u>Date</u>
HREA	1	03/03/2022
Site Specific Assessment, PI signed	1	03/03/2022
Victorian Specific Module, Mercy Health	1	03/03/2022
Protocol	1	14/01/2022

Pelvic Floor Disability Index	1	01/03/2022
Patient Global Impression of Improvement form	1	01/03/2022
PICF, Mercy Health	1	11/01/2022
POP/UISF Questionnaire	1	01/03/2022
Incontinence Impact Questionnaire, Short Form IIQ-7	1	01/03/2022
<i>Noted -</i>		
HREA Mercy Health signature pages, PI signed		01/03/2022
CV – L Schierlitz		
GCP certificate – L Schierlitz		

In all future correspondence, please quote the project reference number: **2022-005**.

The Mercy Health HREC is a constituted and registered committee and functions in accordance with the National Health and Medical Research Council *National Statement on Ethical Conduct in Human Research 2007 (updated 2018)*. In accordance with NHMRC Guidelines, approval is subject to:

1. Immediate notification to the Administration Officer, Mercy Health HREC of any serious adverse effects on participants
2. Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project
3. Notification and reasons for ceasing the project prior to its expected date of completion
4. The submission of a progress report annually for the duration of the project
5. The Mercy Health HREC approval of any proposed modifications to the project
6. The submission of a final report and papers published on completion of the project.

Please also note:

7. Consent Forms must be available for audit by the Mercy Health HREC and retained for the period required by law
8. The Principal Investigator, upon leaving the Institution, must inform the Mercy HREC of a nominated replacement person.

Extensions:

If an extension of ethics approval is required, you must contact the HREC office before the current ethics approval expires. A progress report, using the latest form must accompany your request.

Progress Report:

Continuation of ethics approval is contingent on submission of an annual progress report. Failure to comply with this requirement may result in suspension of the research. A current progress report form is available from the [website](#).

Amendments:

Amendment requests to approved research can be made at any time. The Mercy Health Amendment Request Form must be submitted, along with copies of any additional or amended documentation showing tracked changes. A current Amendment Request Form is available from the [website](#).

Governance:

Please note that this letter confirms the ethical approval of your research only. Local governance approval must also be obtained before the research can commence at the listed site/s.

If you have any queries, please do not hesitate to contact the Administrative Officer, Mercy Health Human Research Ethics Committee on 8458 4808 or email ethics@mercy.com.au.

Yours sincerely,



Mr Tim O'Leary

Chair, Mercy Health Human Research Ethics Committee