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30 August 2021

Dr Avelyn Wong
c/o A/Prof Emma Readman
Mercy Hospital for Women
163 Studley Road
Heidelberg, VIC. 3084

Dear Dr Wong,

Re: 2021-049 – A randomised controlled trial evaluating the use of a multimedia video to improve consent in patients undergoing total laparoscopic hysterectomy

I am pleased to advise that your application has been considered by the Expedited Working Group of Mercy Health Human Research Ethics Committee (HREC) who are delegated to review and approve low risk research proposals. The Expedited Working Group is satisfied that the study meets the requirements of the National Statement on Ethical Conduct in Human Research (2007- updated 2018).

This approval is effective immediately and enables you to commence the study from the date of this letter. The approval will be noted by the Mercy Health HREC at its next meeting on 12 October 2021 for endorsement. No further correspondence will be provided unless the HREC requires additional information.

The research was approved as **low risk** research.

Approval

The HREC approval is from **31 August 2021 until 31 August 2022**.

Approval is given in accordance with the research conforming to the National Statement on Ethical Conduct in Human Research 2007 (updated 2018). Approval is given for this research project to be conducted at the following sites:

- **Mercy Hospital for Women**

Approved documents

<u>Document</u>	<u>Version</u>	<u>Date</u>
Application for HREC Review of Low Risk Research	1	23/07/2021
Low Risk Checklist		23/07/2021
VSM, section 2		25/07/2021

Protocol	2	05/07/2021
Participant Information and Consent Form	3	30/08/2021
Questionnaires	2	25/07/2021
<i>Noted -</i>		
Peer review letter		12/04/2021
Researcher Declaration, signed – A Wong; E Readman; L Ellett		23/07/2021
CVs – A Wong; E Readman; L Ellett		
GCP certificate – A Wong		

In future correspondence please always quote the given project number: **2021-049**.

Researcher Responsibilities

The HREC is constituted 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 the NHMRC Guidelines, approval is subject to:

1. Immediate notification to the Administration Officer, The Mercy Health HREC and sponsor, 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 completion of an annual progress report 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 note that continuation of ethics approval is contingent on submission of an annual progress report, and failure to comply with this requirement may result in suspension of the research. 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.

Amendments:

Amendment requests to approved research can be made at any time. A 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](#).

Extensions:

If an extension of ethics approval is required, you must contact the HREC office before the current ethics approval expires. A completed Progress Report, using a current form can be submitted for making an extension 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](#).

Governance:

Please note this letter confirms the ethical approval of your research only.
For Above-Low Risk research - local governance clearance must also be obtained before the research can commence at the listed site/s.
For Low Risk research - governance clearance will be finalised by the HREC Administration Officer. This study may proceed from date of this letter and you will only be contacted if there is a governance matter needing to be addressed.

If you have any queries, please do not hesitate to contact the Administration 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