The Royal Melbourne Hospital

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Ethical Approval

Royal Melbourne Hospital Human Research Ethics Committee

A/Professor Wen Kwang Lim
Department of Aged Care
Royal Melbourne Hospital
Parkville 3052 VIC

19 May 2022

Dear A/Professor Wen Kwang Lim

HREC Reference Number: HREC/84300/MH-2022

ERM Reference Number: RMH84300

Royal Melbourne Hospital Site Reference Number: 2022.045

Project Title: IMPART - IMproving PAlliative care in Residential aged care using Telehealth

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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 (2007). 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 (2007), 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: 18 May 2022

Ethical approval for this project applies at the following sites:

Site
• Royal Melbourne Hospital VIC
• The National Ageing Research Institute VIC
• Austin Health VIC
• Northern Health VIC
• Monash University VIC

Approved Documents:

The following documents have been reviewed and approved:

Document	Version	Date
Protocol	2	21 April 2022
Master Resident Patient Information Sheet and Consent Form	2	26 April 2022

Master Person Responsible/ Medical treatment decision maker Participant Information Sheet and Consent Form	2	26 April 2022
Master Family/ Friend Carer Participant Information Sheet and Consent Form	2	26 April 2022
Master Participant Information Sheet/Consent Form - Staff	2	26 April 2022
Master Form for Withdrawal of Participation - Resident	2	26 April 2022
Master Form for Withdrawal of Participation – Family/Friend Carer	2	26 April 2022
Master Form for Withdrawal of Participation - Staff	2	26 April 2022
Master Form for Withdrawal of Participation - Person Responsible/Medical treatment decision maker	2	26 April 2022
Master Participant Consent Form for the release of Services Australia information	1	30 March 2022
Master Services Australia Participant Withdrawal of Consent Form	1	30 March 2022
Staff End of Life Care Survey	2	21 April 2022
Family/ Proxy Post Death Survey	2	26 April 2022
Family Proxy Assessment of Quality of Life	1	28 April 2022
Advertising Flyer	2	21 April 2022
Invitation Letter for Bereaved Families	2	21 April 2022
Mental Health Support Resource Sheet	2	26 April 2022
Invitation Letter for Medical Treatment Decision Maker	2	21 April 2022
Templates for Resident File Audit	1	30 March 2022
Needs Analysis Checklist	1	30 March 2022
Action plan template	1	30 March 2022
Activity Log	1	30 March 2022
Resident Assessment of Quality of Life	1	30 March 2022
Residential aged care facility information	1	30 March 2022
Participant Information Document for the release of Services Australia information	1	30 March 2022
Invitation Letter for Medical Treatment Decision Maker	1	30 March 2022

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 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://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting

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)