



Office of Research and Ethics

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1 September 2021

Dr Amy Dennett
Department of Allied Health Clinical Research Office
Level 2, 5 Arnold St,
Box Hill VIC 3128

Dear Dr Dennett,

Study Title: TeleCaRe: Expanding delivery of Cancer Rehabilitation via telehealth

Principal Investigator: Amy Dennett

Associate Investigators: Nicholas Taylor, Katherine Harding, Phillip Parente, Lauren Lynch, Nora Shields, Casey Peiris & Christian Barton

ERM Project ID: 74698

Eastern Health Site Reference Number: E21-012-74698

Further to HREC correspondence sent on 18Jun2021, and 31Aug2021 and responses received 24Aug2021, 31Aug2021 & 01Sep2021 including a final series of amendments and clarifications.

I am pleased to advise that the above study has received full ethical approval from the Eastern Health Human Research Ethics Committee (HREC). The study has received full governance authorisation also from the Office of the Chief Executive Officer or delegate at Eastern Health and may commence at the nominated site.

The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007 inclusive of all updates) (**National Statement**). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (**NHRMC**) National Statement and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles (HPP's) described in the Health Records Act 2001 (Vic).

HREC Final Approval Date: 27Aug2021

Research Governance Authorisation: 01Sep2021

Ethical approval for this project applies at the following site(s): Box Hill Hospital, Healesville Hospital and Yarra Valley Health

Approved Documents:

The following documents have been reviewed and approved by the HREC:

Document	Version	Dated
Human Research Ethics Application (HREA) – ERM Review Reference: HREC/74698/EH-2021-279402	2	24Aug2021
Protocol	2	18Aug2021
Participant Information Sheet and Consent Form (PICF)	2	18Aug2021
Victorian Specific Module (VSM)	N/A	20May2021

The following documents have been reviewed and authorised by the Office of Research and Ethics (Research Governance):

Document	Version	Dated
Site Specific Assessment (SSA) – ERM Review Reference: SSA/74698/EH-2021-280424	2	01Sep2021

Approval is subject to:

1. The Principal Researcher is to ensure that all associate researchers are aware of the terms of approval and to ensure the project is conducted as specified in the application and in accordance with the National Statement.
2. Immediate notification to the Office of Research & Ethics of any serious adverse events on participants.
3. Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project.
4. Notification of any changes to personnel on the study.
5. Notification and reasons for ceasing the project prior to its expected date of completion.
6. Notification of amendments to the study.
7. Submission of an annual report due in February each year for the duration of the study (report template is [here](#)).
8. Submission to the HREC of any proposed modifications to the project or documents as approved by the HREC and noted above.
9. Submission of a final report and papers published on completion of the project.
10. Projects may be subject to an audit or any other form of monitoring by the Eastern Health Office of Research & Ethics at any time.

Confidentiality, Privacy & Research:

Research data stored on personal computers, USBs and other portable electronic devices must not be identifiable. No patients' names or UR numbers must be stored on these devices. Electronic

storage devices must be password protected or encrypted. The conduct of research must be compliant with the conditions of ethics approval and Eastern Health policies.

Publications:

It is very important that the role of Eastern Health including the investigator's affiliation (if appropriate) is acknowledged in publications.

Composition of the HREC

We confirm at the meetings at which the above project was considered, the Committee fulfilled the requirements of the NHMRC National Statement in that it contained men and women encompassing different age groups and included people in the following categories:

HREC Members

Chairperson

Lay Man

Lay Woman

Lawyer

Person/s fulfilling a Pastoral Care Role

Person/s with Counselling Experience

Person/s with Current Research Experience

Please quote the reference number **E21-012-74698** in all future correspondence.

Yours sincerely



Amy Tang
Research Ethics and Governance Officer
Eastern Health Office of Research and Ethics

On behalf of

1. Eastern Health Human Research Ethics Committee (Ethics Approval)
2. Executive Director of Research (Site Research Governance Authorisation)