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Our Ref: HREC Final Approval



13 January 2016

Human Research Ethics Committee
Metro North Hospital and Health Service
The Prince Charles Hospital
Building 14
Rode Road, Chermside QLD 4032

Professor Darren Walters
C/- Dr Mohanraj Karunanithi
Level 5 - UQ Health Sciences Building
901/16
Royal Brisbane & Women's Hospital
Herston QLD 4029

Dear Professor Walters

Re: HREC/15/QPCH/256: A mobile based multidisciplinary virtual clinic for patients with Heart Failure: A Controlled Randomised Trial of MoTER-HF

Thank you for submitting the requested documents for the above project for further review which was received on 22 December 2015. This project was considered by Metro North Hospital and Health Service - The Prince Charles Hospital Human Research Ethics Committee (HREC).

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)*, *NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

I am pleased to advise that the Human Research Ethics Committee has granted final approval of this research project. The documents reviewed and approved for the above mentioned project include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Application (AU/1/B381216)		
Protocol	1	03 September 2015
Patient Information Sheet/Consent Form: Clinician Pre-Study Survey	1	20 December 2015
Patient Information Sheet/Consent Form: Patients Pre-Study Survey	1	20 December 2015
Patient Information Sheet/Consent Form: Randomised Control Trial	1	20 December 2015
Questionnaire: 8-Item Morisky Scale	1	20 December 2015
Questionnaire: DASS 21 Quick Score	1	08 December 2015
Questionnaire: EQ-5D	1	20 December 2015
Questionnaire: 2007/001 Heart Failure Learning Style Needs Inventory	1	08 December 2015
Questionnaire: STOFHLA (Australian Version)	2	20 December 2015
Questionnaire: MoTER 8 Week Survey	1	20 December 2015

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Questionnaire: Mentor End of Trial	1	20 December 2015
Questionnaire: Focus Group Questions	1	20 December 2015
Participant Survey Script	1	08 December 2015
Questionnaire: Mentor 6 months survey	1	22 September 2015
Response to Request for Further Information		22 December 2015
Questionnaire: Pew-Internet-Health Online	1	22 September 2015

This information will be tabled at the next meeting on 28 January 2016 for noting.

Please note the following conditions of approval:

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
 - a. Unforeseen events that might affect continued ethical acceptability of the project.
 - b. Serious Adverse Events that materially impact on the continued ethical acceptability of the project. In addition the Investigator must provide, at least six monthly, a summary of serious adverse events, in the specified format, including a comment as to suspected causality.
2. Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the HREC for review. Major amendments should be reflected in a cover letter from the principal investigator, providing a description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study. Hard copies of the revised amendments, the cover letter and all relevant updated documents with tracked changes must also be submitted to the HREC coordinator as per standard HREC SOP. Further advice on submitting amendments is available from http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp
3. Amendments to the research project which only affect the ongoing site acceptability of the project are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r (by-passing the HREC).
4. Proposed amendments to the research project which may affect both the ethical acceptability and site suitability of the project must be submitted firstly the HREC for review and, once HREC approval has been granted, submitted to the RGO.
5. Amendments which do not affect either the ethical acceptability or site acceptability of the project (e.g. typographical errors) should be submitted in hard copy to the HREC coordinator. These should include a cover letter from the principal investigator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.
6. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.
7. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.
8. The Hospital & Health Service Administration and the Human Research Ethics Committee may inquire into the conduct of any research or purported research, whether approved or

not and regardless of the source of funding, being conducted on hospital premises or claiming any association with the Hospital; or which the Committee has approved if conducted outside The Prince Charles Hospital & Health Services.

HREC approval is valid for **3 years** from the date of this letter (**13th December 2019**).

Should you have any queries about the HREC's consideration of your project please contact the Executive Officer on the above phone numbers or email addresses. The HREC terms of Reference, Standard Operating Procedures, membership and standard forms are available from http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Hospital & Health Services CEO or Delegate of that site has been obtained.

A copy of this approval must be submitted to the relevant Hospital & Health Services Research Governance Officer/s or Delegated Personnel with a completed Site Specific Assessment (SSA) Form for authorisation from the CEO or Delegate to conduct this research at the site/s.

Once authorisation to conduct the research has been granted, please complete the Commencement Form http://www.health.qld.gov.au/tpch/documents/form_notification.dot and return to the office of the Human Research Ethics Committee.

The HREC wishes you every success in your research.

Yours faithfully



Dr Russell Denman
Chair

**HUMAN RESEARCH ETHICS COMMITTEE
METRO NORTH HOSPITAL AND HEALTH SERVICE**

List of approved Sites:

No.	Site
1.	The Prince Charles Hospital

The members present at the Metro North Hospital & Health Service, Human Research and Ethics Committee meeting on the when the approval was granted for is listed in the table below.

Attendees	Present	Apology
(Chair) Medical Representative Cardiology (a/f) [M]		
(Acting Deputy Chair) Medical Representative - Geriatrics (f) [F]		
Layman (b) [M]		
Research Scientist (c) [F]		
Director of Pharmacy [M]		
Medical Representative Psychiatry (f) [M]		
Laywoman (b) [F]		
Medical Representative O & G (c) [F]		
Executive Director, Medical Services [M]		
Senior Researcher (f) [M]		
Executive Officer - Research and Ethics [F]		
Legal Representative (e) [F]		
Nursing Representative (c) [M]		
Religious Representative (d) [F]		
Medical Representative - Thoracic (f) [M]		
Medical Representative - Anaesthetics/Intensive Care (f) [M]		

This is also to certify that TPCHMNHSHREC is a NHMRC accredited Ethics Committee. Our Registered Number is EC00168.

Our accredited Ethics Committee is organised, complies and operates within the GCP and ICH Guidelines.

Note: The composition of the HREC is constituted in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (March 2007).

Please be advised that in the instance of an investigator being a member of the HREC, they are absented from the decision making process relating to that study.

For further information please the Research, Ethics & Governance Office on 3139 4198.