



6 March 2017

Mrs Karen Royals
Respiratory Department
The Queen Elizabeth Hospital

Dear Mrs Royals,

Project title: Chronic Obstructive Pulmonary Disease (COPD) management at home to reduce emergency department presentations: a randomised control, feasibility trial.

HREC reference number: HREC/16/TQEH/268

CALHN reference number: Q20161113

RE: Ethics Application APPROVAL

Thank you for submitting the above project for ethical and scientific review. The project was first considered by The Queen Elizabeth Hospital Human Research Ethics Committee (TQEH/LMH/MH) at its meeting held on 5 December 2016.

The HREC has reviewed all responses, and I am pleased to advise that your protocol has been granted full ethics approval and meets the requirements of the *National Statement on Ethical Conduct in Human Research, incorporating all updates*. The documents reviewed and approved include:

Document	Version	Date
NEAF Application	AU/15/1F3A29	21 November 2016
Protocol	7	28 February 2017
COPD at Home Phone Recruitment Script	7	28 February 2017
Letter of Invitation	3	17 January 2017
Participant Information Sheet and Consent Form	10	2 March 2017
Case Report Form – Patient Demographics	-	-
Modified Medical Research Council Dyspnoea Scale	1	17 January 2017
Beck Anxiety Inventory	1	17 January 2017
Beck Depression Inventory	1	17 January 2017
SF-36 Questionnaire	-	-
Partners in Health Scale	-	2013
Cue and Response Interview	-	2010
COPD Self-Efficacy Scale	1	17 January 2017
COPD Assessment Test	-	24 February 2012
Respiratory Nurse Clinical Assessment	-	17 January 2017
Contact Instructions	2	17 January 2017
RNS and ECP Participant Demographic	-	17 January 2017
Advance Care Directive Form	-	-
COPD Action Plan	-	-
Medical Log	1	17 January 2017
Medication Record	1	-
RDR Chart	-	June 2014
RNS Information	-	July 2013
COPD Consumer Information Sheet	-	-
Advance Care Directive Form & Kit	-	-
Breathing Techniques Information Sheet	-	February 2009

Depression Stress Anxiety Information Sheet	-	February 2009
Pulmonary Rehabilitation Information Sheet	-	-
Falls and Injury Prevention Information Sheet	-	May 2011
Falls – Making Home your Haven Information Sheet	-	May 2011
Eating Well with Lung Disease Information Sheet	-	February 2009
Contenance & Lung Disease Information Sheet	-	February 2009
Infection Control Information Sheet	-	-
Quality of Life Through Patient Support Information Sheet	-	December 2013
GP Letter	-	17 January 2017
Additional Respiratory Assessment	-	17 January 2017
Hospital Switchboard Instructions	-	17 January 2017
Reported Exacerbations	-	17 January 2017
Rapid Response Assessment	-	-
SAAS ECP Work Instruction	2	16 November 2015
ECP RNS Summary	1	-
Check Up After ED Presentation or Hospital Admission	-	17 January 2017
Semi-structured Interview	1	17 January 2017
1 Week Review Form	1	17 January 2017
3 Month Review Form	1	17 January 2017
6 Month Final Review Form	1	17 January 2017
6 Month RNS Review Form	-	-
Adverse Events Form	-	17 January 2017
Study Violations Form	-	17 January 2017
Participant Completion/Withdrawal	-	17 January 2017

Sites covered by this approval:

- **Royal Adelaide Hospital, SA: PI – Mrs Karen Royals**
- **The Queen Elizabeth Hospital, SA: PI – Mrs Karen Royals**

HREC approval is valid for **5 years** from **6 March 2017 to 6 March 2022**.

Please quote the **HREC Reference number, HREC/16/TQEH/268** and the **CALHN Reference number, Q20161113** allocated to your study on all future correspondence.

GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:

1. For all clinical trials, the study must be registered in a publicly accessible trials registry prior to enrolment of the first participant.
2. This HREC is certified with the NHMRC for National Mutual Acceptance of Single Ethical and Scientific Review of Multi-centre Clinical Trials. This HREC will act as a 'lead HREC' for the purpose of this ethics approval. Any study sites that are not listed on this letter are not covered by this ethics approval. Any study-sites that wish to be added must contact the CPI, who must write formally to this HREC requesting the additional study site.
3. Adequate record-keeping is important and must be maintained in accordance with GCP, NHMRC and state and national guidelines. If the project involves signed consent, you should retain the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them in the future if necessary. The duration of record retention for all clinical research data is 15 years.
4. Researchers must notify the HREC of anything which might warrant review of the approval of the study, or which warrant new information being presented to research participants, including:
 - (a) adverse events which warrant protocol change or notification to research participants;

- (b) changes to the protocol;
 - (c) changes to the safety or efficacy of the investigational product, device or method;
 - (d) premature termination of the study.
5. Confidentiality of the research participants shall be maintained at all times as required by law.
 6. Approval is valid for **5 years** from the date of this letter, after which an extension must be applied for.
 7. Annual review reports must be submitted to the HREC, every 12-months on the anniversary of the above approval date. Each site covered by this HREC must submit a report, and it is the responsibility of the Coordinating Principal Investigator to ensure this is provided to the TQEH HREC Executive Officer, within 10 working days on each anniversary of the approval date, using the Annual Review Form available at: <http://www.basilhetzelinstitute.com.au/research/information-for-researchers/human-research-ethics-committee/>
 8. The HREC must be advised with a final report or in writing, and a copy of any published material within 30 days of completion of the project.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at any site until separate authorisation from the Chief Executive or delegate of that site has been obtained. For any queries, please contact the CALHN Governance Office:
Health.CALHNResearchGovernanceIP&Contracts@sa.gov.au

This Committee is constituted in accordance with the NHMRC *National Statement on the Ethical Conduct of Human Research (2007)* incorporating all updates.

Should you have any queries about the HREC's consideration of your project, please contact Mrs Heather O'Dea, HREC Executive Officer on 08 8222 6841 or Health.CALHNResearchEthics@sa.gov.au

The HREC wishes you every success in your research.

Yours sincerely



Professor Richard E Ruffin
Chairman, Human Research Ethics Committee (TQEH/LMH/MH)

RR:HO

Cc: Site Research Governance Officer(s)