



Approval Date: 27 March 2018

HREC Reference number: HREC/18/CALHN/176

CALHN Reference number: R20180324

Mrs Kathryn Lawton
 Respiratory Nursing Service
 The Queen Elizabeth Hospital

Ground Floor, Basil Hetzel Institute for Translational Research
 28 Woodville Road, Woodville SA
 Australia 5000

T : 08 7117 2229

T : 08 8222 6841

Dear Mrs Lawton,

E : Health.CALHNResearchEthics@sa.gov.au

Project Title: Management of bronchiectasis: What are the barriers and enablers to bronchiectasis management and the use of guidelines in outpatient care?

Thank you for submitting the above project for ethical review. This project was considered by the Chairman of the Central Adelaide Local Health Network Human Research Ethics Committee. 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 (2007) incorporating all updates. The documents reviewed and approved include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter	-	20 March 2018
LNR Ethics and Governance Application Form	-	-
Bronchiectasis Management Guideline Interview Protocol	4	22 March 2018
Participant Information Sheet Bronchiectasis Health Professional	3	22 March 2018
Participant Information Sheet Bronchiectasis Patients	3	22 March 2018
Health Professionals Recruitment Flyer	1	17 January 2018
Patient Recruitment Flyer	1	17 January 2018
Heads of Unit Recruitment Script, Letter, Email Health Professional	1	15 January 2018
Recruitment Script, Letter, Email Health Professional	1	15 January 2018
Recruitment Script, Letter, Email Patient	1	15 January 2018
Bronchiectasis Questionnaire: Respiratory Physicians	1	22 December 2017
Bronchiectasis Questionnaire: Respiratory Nurses	1	22 December 2017
Bronchiectasis Questionnaire: Respiratory Physiotherapists	1	17 January 2017
Bronchiectasis Questionnaire: Patient	1	05 January 2017
The E-FACED score severity	-	2017
Quality of Life Questionnaire: Bronchiectasis	3.1	2012
Interview Moderator Guide (Respiratory Physicians)	1	05 March 2018
Interview Moderator Guide (Respiratory Nurses and Physiotherapists)	1	17 January 2018
Moderator Guide (Bronchiectasis Patients)	1	17 January 2018
Master Sheet: Protocol Numbers	-	-
Data Collection Template: Patients	1.1	18 January 2018

Sites covered by this approval:

- Royal Adelaide Hospital, SA : Mrs Kathryn Lawton
- The Queen Elizabeth Hospital, SA : Mrs Kathryn Lawton

HREC approval is valid from **27 March 2018 to 27 March 2023**

GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:

1. This HREC is the South Australian '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. For any SA study-sites within the public health system that are proposed to be added, the CPI must write formally to this HREC requesting the additional study site and a separate formal letter will be issued.
2. Adequate record-keeping must be maintained in accordance with GCP, NHMRC and state and national guidelines. The duration of record retention for all clinical research data is 5 years from the date of publication.
3. Researchers are required to immediately report to this HREC anything which might warrant review of ethical approval of the study, 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.
4. The Committee must be notified within 72 hours of any Urgent Safety Measures (USMs) occurring at this or any approved sites.
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. Investigators are responsible for providing an annual review to the CALHN HREC Executive Officer each anniversary of the above approval date, within 10 working days, using the Annual Review Form available at: <https://www.rahresearchfund.com.au/rah-research-institute/for-researchers/human-research-ethics/>
8. The REC must be advised with a report or in writing within 30 days of completion.

Should you have any queries about the HREC's consideration of your project, please contact Ms Heather O'Dea on 08 8222 4139, or Health.CALHNResearchEthics@sa.gov.au.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a SA Health site until governance authorisation at that site has been obtained. Please contact the CALHN Research Office Health.CALHNResearchLNR@sa.gov.au

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

The HREC wishes you every success in your research.

Yours sincerely



**Ian Tindall
CHAIRMAN
CALHN HUMAN RESEARCH ETHICS COMMITTEE
27 March 2018**