

**Approval Date: 26 March 2018**

HREC Reference number: HREC/18/CALHN/150

CALHN Reference number: Q20180303

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

Ms Zoe Kopsaftis
 Respiratory Medicine Unit
 The Queen Elizabeth Hospital

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E : Health.CALHNResearchEthics@sa.gov.au

Dear Ms Kopsaftis,

Project Title: Exploring health professional and patient perspectives of best practice care for people with chronic obstructive pulmonary disease, in the hospital and outpatient setting

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	-	13 March 2018
LNR Ethics and Governance Application Form	-	9 March 2018
Research Protocol	2.0	13 March 2018
Participant Information Sheet and Consent Form: COPD	1.0	6 March 2018
Participant Information Sheet and Consent Form: COPD	1.0	6 March 2018
Head of Unit email for Health Professionals	1.0	6 March 2018
Recruitment email – Health Professionals	1.0	4 March 2018
Questionnaire: COPD Patients	1.0	25 February 2018
Chronic Respiratory Questionnaire (Self Reported)	-	2001
Recruitment Flyer	1.0	6 March 2018
Recruitment Telephone Script	1.0	4 March 2018
Semi-structured interview moderator guide: patients with COPD	1.0	6 March 2018
Questionnaire Health Professions	1.0	25 February 2018
One-on-one interview moderator guide: Health Professionals	1.0	22 February 2018

Sites covered by this approval:

- Royal Adelaide Hospital, SA : Ms Zoe Kopsaftis
- The Queen Elizabeth Hospital, SA : Ms Zoe Kopsaftis

HREC approval is valid from **26 March 2018 to 26 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.rahrefund.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
26 March 2018**