

## Danny Eckert

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**From:** no\_reply@gems.sahealth.sa.gov.au  
**Sent:** Tuesday, 15 June 2021 1:53 PM  
**To:** Thomas Altree  
**Cc:** Danny Eckert; Health.SALHNOfficeforResearch@sa.gov.au; karen.saxty@sa.gov.au; Gianfranco.Carosi2@sa.gov.au  
**Subject:** 2021/HRE00178: Application HREA - Approved

Date of Decision Notification: 15 Jun 2021

Dear Dr Thomas Altree,

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

**2021/HRE00178:** The effects of morphine on breathlessness and sleep in chronic obstructive pulmonary disease: A randomised, double-blind, placebo controlled cross-over study.

This project was considered by the **Southern Adelaide Clinical Human Research Ethics Committee** at its meeting held on **#{ApprovalDate}** and was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007).

This project has been approved to be conducted at the following sites:

- Southern Adelaide Local Health Network (Site)

The following documentation was reviewed and is included in this approval:

- Clinic Flyer landscape Morphine in COPD and Sleep-1-01-May-2021
- Clinic Flyer portrait Morphine in COPD and Sleep-1-01-May-2021
- Cover Letter Morphine in COPD and Sleep-1-01-May-2021
- Docusate and sennosides TGA monograph-1-01-May-2021
- Kapanol Australian Product Information-1-01-May-2021
- PICF Morphine in COPD and Sleep v1.2 clean copy-1.2-27-May-2021
- Protocol v1.1 clean copy-1.1-27-May-2021

[Application Documents](#) - (Please note : Due to security reasons, this link will only be active for 14 days.)

The Human Research Ethics Application reviewed by the HREC was:

Version: 1.02

Date: 11 Jun 2021

It is noted that the Southern Adelaide Clinical Human Research Ethics Committee is constituted in accordance with the National Statement on Human Conduct in Research, 2007 (Updated 2018) (NHMRC). The approval is for a period of **3 years from the date of this e-mail (15 Jun 2021)**, on condition of the submission of annual reports for both ethics and governance applications.

We wish you all the best with the project and remind you that any changes to the application and safety reports

will need to be submitted and reviewed by the approving HREC prior to implementation. You must immediately report to the HREC anything that may change the ethics or scientific integrity of the project.

**This email constitutes ethical and scientific approval only.**

This project cannot proceed at any site until separate research governance authorisation has been obtained from the institution under whose auspices the research will be conducted at that site.

**This HREC is constituted and operates in accordance with the National Statement on Ethical Conduct in Human Research (2007) (Updated 2018). The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.** Confidentiality of the research subjects must be maintained at all times as required by law.

If your study involves a tertiary institution, contact the University to ensure compliance with University requirements prior to commencement of this study. This includes any insurance and indemnification.

A report and a copy of any published material should be forwarded to the HREC at the completion of the project. If the project is discontinued before its completion, the HREC must be advised immediately and provided with reasons for discontinuing the project.

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below. We look forward to managing this application with you throughout the project lifecycle.

Kind Regards,

Dominic How  
SAC HREC Executive Officer

on behalf of

Professor Bill Heddle  
Chair  
Southern Adelaide Clinical Human Research Ethics Committee