

MELBOURNE HEALTH

Office for Research
The Royal Melbourne Hospital
Level 2 South West
300 Grattan Street
Parkville VIC 3050
Australia

Telephone: +61 3 9342 8530
Facsimile: +61 3 9342 8548
Email: research@mh.org.au
thermh.org.au
ABN 73 802 706 972

APPROVAL OF AMENDMENT

19 March 2019 (updated 15 May 2019)

Dear Prof Colin Royse,

HREC Reference Number: HREC/17/MH/325

SSA Reference Number: SSA/18/MH/23

Local Project Number: 2017.266

Research Title: The Supervised Early Resistance Training (SEcReT) Study: progressive resistance training following median sternotomy

Type of review: HREC and Governance Review

I am pleased to advise that the amendment to the above project has been reviewed and approved by the Melbourne Health HREC (ethical approval). This approval applies to all sites for which the Melbourne Health HREC has issued ethical approval. The amendment has also been approved to be conducted at Melbourne Health (governance approval). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHRMC) National Statement on Ethical Conduct in Human Research (2007), and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

Amendment Approval Date: 19 March 2019

Approved Documents: Ethics and Governance Approval

- SEcReT Protocol Version 5, dated 17 December 2018
- SEcReT Patient Perception Telephone Script Version 1, dated 02 October 2018
- SEcReT CRF Version 3
- SEcReT Patient Perception questions Version 2, dated 17 December 2018

Approved Documents: Ethics Approval

- SEcReT PICF Master Version 4, dated 17 December 2018

Approved Documents: Governance approval

- RMH SEcReT PICF Version 4, dated 17 December 2018 (based on SEcReT PICF Master Version 4, dated 17 December 2018)

Please refer to the Melbourne Health Office for Research website to access guidelines and other information and news concerning research at: <https://www.thermh.org.au/research/researchers>

Please Note: Template forms for reporting Amendments, Adverse Events, Annual Report/Final Reports, etc. can be accessed from: <https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting>

For any queries about this matter, please contact the HREC Manager on 03 9342 8530 or via email on: research@mh.org.au

Yours sincerely,

A handwritten signature in black ink, appearing to read 'P. Colman', with a large, stylized initial 'P'.

Professor Peter Colman
Chair – Melbourne Health Human Research Ethics
Committee (HREC)

A handwritten signature in black ink, appearing to read 'Angela Watt', written in a cursive style.

Dr Angela Watt
Director Research Governance and Ethics