

# MELBOURNE HEALTH

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## APPROVAL OF AMENDMENT

31 May 2019

Dear Dr Bower

**HREC Reference Number:** HREC/43007/MH-2018-67544

**SSA Reference Number:** SSA/43007/MH-2018

**Local Project Number:** 2018.246

**Research Title:** An evaluation of the safety and efficacy of photobiomodulation on symptoms of an overactive bladder

**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:** 31 May 2019

**Approved Documents:** Ethics & Governance Approval

- Protocol version 3.0 dated 29 April 2019
- PICF version 3.0 dated 29 April 2019
- Victorian Specific Module version 3.0 dated 29 April 2019

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](mailto:research@mh.org.au)

Yours sincerely,



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



Dr Angela Watt  
Director Research Governance and Ethics