



Metro South Health
Research

Enquiries to: Metro South Human Research
Ethics Committee
Telephone: 07 3443 8049
Reference: AM/2019/QMS/38187
Email: MSH-Ethics@health.qld.gov.au
Amendment: AM03

Dr Stuart Bailey
ENT Principal House Officer
Princess Alexandra Hospital

Dear Dr Bailey,

HREC Reference: HREC/17/QPAH/730

Protocol Title: The use of thermoresponsive, mucoadhesive solgels in post endoscopic sinus surgery cavities

The Office of the Metro South Human Research Ethics Committee noted and approved the following:-

Document	Version	Date
Notification of amendment submitted via Ethical Review Manager (ERM) with respect to the following; <ul style="list-style-type: none">- Change in procedure: alteration to the excipients in the solgel, updated safety profile of excipients- Addition of Angelica Lynch as an Investigator	2	22/09/2019
Trial 3 PICF v 4.0 clean	4	26/08/2019
HREC:17:QPAH:730 coverletter		26/08/2019
Trial 3 PICF v 4.0 track changes	4	26/08/2019
Trial 3 Solgels in post ESS patients PROTOCOL v 5.0 clean	5	21/08/2019
Trial 3 Solgels in post ESS patients PROTOCOL v 5.0 track changes	5	21/08/2019
Trial 3 Solgels in post ESS patients PROTOCOL v 6.0 clean	6	21/08/2019
Trial 3 Solgels in post ESS patients PROTOCOL v 6.0 track changes	6	21/08/2019

The Metro South Hospital and Health Service HREC is constituted and operates in accordance with the National Health and Medical Research Council's "National Statement on Ethical Conduct in Human Research (2007)", NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) and the "CPMP/ICH Note for Guidance on Good Clinical Practice".

This will be ratified by the HREC at its 5th November 2019 meeting.

Please provide a copy of this approval letter to the Research Governance Office.

It should be noted that all requirements of the original approval still apply. Please continue to provide at least annual progress reports until the study has been completed.

If you have any queries please do not hesitate to contact the Human Research Ethics Committee office on +617 3443 8049.

Yours sincerely,

A handwritten signature in black ink that reads "SB Campbell". The signature is written in a cursive style.

A/Prof Scott Campbell
Chair
Metro South Hospital and Health Service
Human Research Ethics Committee (EC00167)
Metro South Research
26 / 09 / 2019