

14/10/2021

Dear Professor David Gillatt,

Reference No: 52021206932389

Title: 2069 - TP002 - A 56 week, Double-Blind, Randomised Study to Evaluate the Efficacy of Testosterone, With and Without DHA Supplementation on Cerebral Amyloid Load in Men with Subjective Memory Complaints

I am pleased to advise that ethical approval has been granted for project extension to 11 December 2024. Amendment dated **15 September 2021**. The documents approved are as follows:

The following documentation has been reviewed and approved by the HREC (Medical Sciences):

- TP002 Protocol version 7.0 Summary of Changes 12-Jul-2021
- TP002 Protocol version 7.0, dated 12-Jul2021 (Tracked and Clean)
- TotAL Study MQ Main PICF v2.6, dated 09-Sep-2021 (Clean and Tracked)
- TotAL Study MQ PGx PICF v2.0, dated 09-Sep-2021 (Clean and Tracked)
- TotAL Study Partner Acknowledgement Form v2.0, dated 09-Sep-2021 (Clean and Tracked)
- TotAL Study MQ Summary Information Sheet Version 1.0 dated 15-Sep-2021
- TP002 Participant Diary Card, Version 4, 22 November 2018

The follow documents have been acknowledged:

- TP002 Letter to Ramsay Health Care WA / SA HREC dated 27May2021 RE: COVID-19 Impact
- TP002 Letter to Ramsay Health Care WA / SA HREC dated 21Apr2020 RE: Unable to Collect CSF Samples
- TotAL Study - PI Statement (Email) dated 14Sep2021 – RE: TP002 Protocol v7

The HREC Terms of Reference and Standard Operating Procedures are available from the Research Services website at:

<https://www.mq.edu.au/research/ethics-integrity-and-policies/ethics/human-ethics>

Please do not hesitate to contact the Ethics Secretariat should you have any questions regarding your ethics application.

The HREC (Medical Sciences) wishes you every success in your research.

Yours sincerely,



Professor Anthony Eyers
Chair, Macquarie University Human Research Ethics Committee (Medical Sciences)

This HREC is constituted and operates in accordance with the National Health and *Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research* (2007, updated July 2018) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*