

2020/ETH01824: Application HREA - Approved

no_reply@regis.health.nsw.gov.au <no_reply@regis.health.nsw.gov.au>

Thu 21/01/2021 3:59 PM

To: Lindsey Brett <lindsey.brett@mq.edu.au>

Cc: Lindsey Brett <lindsey.brett@mq.edu.au>

Date of Decision Notification: 21 Jan 2021

Dear Lindsey Brett,

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

2020/ETH01824: Prevalence of sarcopenia in an Australian geriatric Medical Assessment Unit (MAU)

This Application was reviewed as a **Greater than low risk review pathway** and was considered by the **South Eastern Sydney Local Health District HREC** at its meeting held on 21 January 2021.

The project was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED**.

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 at which the research will take place.

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

- Prince of Wales Hospital

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

- Study Protocol, 2020 ETH01824_sarcopenia prevalence protocol.pdf
- Other, Please specify, Cover letter in response to ethics review 14.01.2021-1-14-Jan-2021
- Application, HREA
- Participant Consent Form, Participant information sheet and consent form - participant-5-14-Jan-2021
- Participant Consent Form, Participant information sheet and consent form - person responsible-5-14-Jan-2021
- Application, Submission_Original

[Application Documents](#) - (link will only be active for 14 days from the decision date. The approved documents are also available to download from forms section of this project in REGIS)

The Human Research Ethics Application reviewed by the HREC was:

Version: 1.04

Date: 14 Jan 2021

The approval is for a period of 5 years from the date of this e-mail (**21 Jan 2021**)

The Coordinating Principal Investigator agrees to:

- provide the HREC with an annual report and the final report when the project is completed at all sites. This will be through the submission of a milestone in REGIS.

- immediately report anything that might warrant review of ethical approval of the project.
- submit proposed amendments to the research protocol, including; the general conduct of the research, changes to CPI or site PI, an extension to HREC approval, or the addition of sites to the HREC before those changes can take effect. This will be through a notification of an amendment in REGIS
- notify the HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.

Submission of annual progress/final reports (milestone), amendments and safety reports should be done through the forms provided in REGIS. Guidance on these processes can be found on the [REGIS website](#).

It is noted that the **South Eastern Sydney Local Health District HREC** is constituted in accordance with the National Statement on Human Conduct in Research, 2007 (NHMRC).

The processes used by the HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

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 study with you throughout the project lifecycle.

Regards,

Patrick Caldwell

Executive Officer | SESLHD Research Ethics & Governance
(02) 9382 2458 | patrick.caldwell@health.nsw.gov.au

