

From: no_reply@regis.health.nsw.gov.au
Subject: 2021/ETH11829: Application HREA - Approved
Date: 15 December 2021 at 10:35
To: zheng.cao@myacu.edu.au
Cc: zheng.cao@myacu.edu.au



Date of Decision Notification: **15 Dec 2021**

Dear Ms Zheng Cao,
Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

2021/ETH11829: Using Muscle Strength as a Predictor for Walking Ability after Stroke

This Application was reviewed as a **Low or negligible risk review pathway** and was initially considered by the **South Eastern Sydney Local Health District HREC** at its meeting held on **14/12/2021**.

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**
- **St George Hospital**

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

- Application, HREA
- Muscle Strength Predict Walking Ability Data Collection Sheet - Version 1 - 27/10/2021
- Other, Muscle Strength Predict Walking Ability_cover letter for request for more information-1/12/2021
- Muscle Strength Predict Walking Ability_Master Copy_Participant Information Sheet and Consent Form -Version 1 - 5/11/2021
- Study Protocol, Muscle Strength Predict Walking Ability_Study Protocol - Version 2 -1/12/2021
- Project Registration

[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: 1.03

Date: 01 Dec 2021

The approval is for a period of 5 years from the date of this e-mail (**15 Dec 2021**)

The Coordinating Principal Investigator will:

- 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
- will notify the HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- submit any necessary reports related to the safety of research participants in accordance with NHMRC Safety and Reporting Guidance. This will be through the Significant Safety Issue or Third Party Breach form in REGIS.
- Interventional trials must be registered on one of the clinical trial registeries e.g. <https://www.anzctr.org.au>.

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 Human 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,
Nitisha Kulkarni
Research Ethics and Governance Officer

Research Ethics and Governance Office
SESLHD-RSO@health.nsw.gov.au