

2020/ETH00833: Application HREA - Approved

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Thu 22/10/2020 10:41 AM

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

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

Date of Decision Notification: 22 Oct 2020

Dear Dr Lindsey Brett,

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

2020/ETH00833: Dementia Training for Physiotherapy Practitioners and Students using Artificial Intelligence-Enhanced Virtual Reality Technology

This Application was reviewed as a **Greater than low risk review pathway** and was initially considered by the **South Eastern Sydney Local Health District HREC** at its meeting held on **INITIAL MEETING DATE**. 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:

- Advertising Material, Stage 2 recruitment poster (V1)-1-04-Jun-2020
- Participant Consent Form, Stage 2 PISCF (pilot test): physiotherapist (V2)-2-26-Aug-2020
- Participant Consent Form, Stage 2 PISCF (focus group): physiotherapist (V2)-2-26-Aug-2020
- Questionnaire, Stage 2 pilot test questionnaire - pre (V2)-2-26-Aug-2020
- Questionnaire, Stage 2 pilot test questionnaire - post (V2)-2-26-Aug-2020
- Questionnaire, Stage 2 pilot test questionnaire - follow-up (V2)-2-26-Aug-2020
- Advertising Material, Stage 1 recruitment poster (V2)-2-26-Aug-2020
- Participant Consent Form, Stage 1 PISCF (observation and focus group): physiotherapist (V2)-2-26-Aug-2020
- Application, Submission_Original
- Participant Consent Form, Stage 1 PISCF (observation and focus group): person responsible (V1)-1-26-Aug-2020
- Study Protocol, Protocol (V3) - tracked changes-1-08-Oct-2020
- Study Protocol, Protocol (V2) - tracked changes-1-26-Aug-2020
- Application Attachment, ProjectRegistration
- Application, HREA
- More Information Required, Cover letter -response to ethics review feedback-1-02-Sep-2020
- More Information Required, Cover letter in response to request for more info-1-08-Oct-2020
- Study Protocol, 2020 ETH00833_AI VR DEM TRAIN PT_Protocol.docx
- Participant Consent Form, Stage 1 PISCF (observation and focus group): older person with dementia (V2)-2-26-Aug-2020

- Questionnaire, VR health screen (V1)-1-24-Jun-2020

[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: 1.02

Date: 09 Oct 2020

The approval is for a period of 5 years from the date of this e-mail (**22 Oct 2020**)

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.
- 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 registries 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 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

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



22/01/2021

Dear Dr Lindsey Mc Caffrey,

Reference No:52020925823005

Title: 9258 Dementia Training for Physiotherapy Practitioners and Students using Artificial Intelligence-Enhanced Virtual Reality Technology

Thank you for submitting the above application for ethical and scientific review. Macquarie University Human Research Ethics Committee HREC EXEC Medical Sciences Committee considered your application.

I am pleased to advise that ethical and scientific approval has been granted for this project to be conducted by Dr Lindsey Mc Caffrey and other personnel: Professor Deborah Richards, Mr Amitoj Thind, Ms Meredith Porte, Associate Professor Taryn Jones, Mr Daniel Treacy .

Approval Date:

This research meets the requirements set out in the *National Statement on Ethical Conduct in Human Research* (2007, updated July 2018) (the *National Statement*).

Standard Conditions of Approval:

1. Continuing compliance with the requirements of the *National Statement*, which is available at the following website:
<http://www.nhmrc.gov.au/book/national-statement-ethical-conduct-human-research>
2. This approval is valid for five (5) years, subject to the submission of annual reports. Please submit your reports on the anniversary of the approval for this protocol.
3. All significant safety issues, that adversely affect the safety of participants or materially impact on the continued ethical and scientific acceptability of the project, must be reported to the HREC within 72 hours.
4. Proposed changes to the protocol and associated documents must be submitted to the Committee for approval before implementation.

It is the responsibility of the Chief investigator to retain a copy of all documentation related to this project and to forward a copy of this approval letter to all personnel listed on the project.

Should you have any queries regarding your project, please contact the Ethics Secretariat on 9850 4194 or by email ethics.secretariat@mq.edu.au

The HREC EXEC Medical Sciences Committee Terms of Reference and Standard Operating Procedures are available from the Research Office website at: <https://www.mq.edu.au/research/ethics-integrity-and-policies/ethics/human-ethics>

The HREC EXEC Medical Sciences Committee wishes you every success in your research.

Yours sincerely,



Professor Anthony Eyers
Chair, HREC EXEC Medical Sciences Committee

