

Contact: Sydney Local Health District Human Research Ethics Committee
Concord Repatriation General Hospital
Concord NSW 2139
Telephone: (02) 9767 5622
Email: SLHD-ConcordEthics@health.nsw.gov.au

Local Ref: CH62/6/2020-199



CONCORD
REPATRIATION GENERAL
HOSPITAL

13 January 2021

Associate Professor Karen Liu
C/- Ms Christine Hill
Western Sydney University
Locked Bag 1797
Penrith NSW 2751

Dear Associate Professor Liu,

Re: Local reference number: CH62/6/2020-099
REGIS ethics application number: 2020/ETH02885
REGIS project ID number: 2020/PID03236
Project title: Feasibility and acceptability of a newly developed rehabilitation program to enhance everyday functioning in people with Parkinson's disease - A pilot study

Thank you for submitting the above research proposal for single ethical and scientific review. This project was first considered by the Sydney Local Health District Human Research Ethics Committee – CRGH at its meeting held on 26 November 2020. This Human Research Ethics Committee (HREC) has been accredited by the NSW Ministry of Health as a lead HREC under the model for single ethical and scientific review.

This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

I'm pleased to advise that final ethical approval has been granted on the basis of the following:

- The research project meets the requirements of the *National Statement on Ethical Conduct in Human Research*.

The documents reviewed and approved include:

| | VERSION | DATE |
|--|------------|------------------|
| Human Research Ethics Application (HREA) | 2 | 02 December 2020 |
| Protocol | 2 | 08 January 2021 |
| Master Information for Participants and Consent Form | 2 | 12 January 2021 |
| Program Outline | 1 | 12 January 2021 |
| Promotion Flyer | 2 | 08 January 2021 |
| Evaluation of program acceptability | 2 | 08 January 2021 |
| Data Collection Form | 2 | 08 January 2021 |
| Master Code Sheet | No version | No date |
| Research Data Management Plan | 2 | 08 January 2021 |
| The Barthel Index (noted) | No version | 1965 |
| Canadian Occupational Performance Measure (noted) | No version | 2000 |
| The Lawton Instrumental Activities of Daily Living Scale (noted) | 23 | 2007 |
| Montreal Cognitive Assessment (noted) | No version | 07 November 2004 |
| The Hoehn and Yahr Scale (noted) | No version | No date |
| Timed Up and Go Test (noted) | No version | No date |

| | | |
|--|------------|------------------|
| Trail Making Test (TMT) Parts A and B (noted) | No version | No date |
| Unified Parkinson's Disease Rating Scale (noted) | No version | 2006 |
| UWS HREC Approval (noted) | No version | 16 July 2019 |
| MOCA Certification – Tess Dedomizio (noted) | N/A | 20 November 2020 |

The HREC has provided ethical and scientific approval for the following sites:

1. Concord Repatriation General Hospital

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at any site until you have submitted a Site Specific Assessment (SSA) Form to the Research Governance Officer (RGO) and received separate authorisation from the Chief Executive or delegate at that site.

Please note the following conditions of approval:

1. HREC approval is valid for five (5) years subject to the supply of an annual progress report. The first report should be sent to the HREC by **13/01/2022**. You must also provide an annual report to the HREC upon completion of the study.
2. You will adhere to the study protocol at all times.
3. Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review.
4. You will notify the HREC, giving reasons, if the project is discontinued at a site before the expected date of completion.
5. You will immediately report anything which might warrant review of ethical approval of the project, including unforeseen events that might affect continued ethical acceptability of the project, (including Significant Safety Issues).
6. It is noted that REDCap will be utilised for the study. Once the REDCap project has been set-up please provide a copy of the REDCap Project Code Sheets with a version number and date to the Ethics Committee for review and approval prior to study commencement. Please note, the SLHD Research Data Manager and REDCap Administrator can be contacted for assistance and bookings via [email](#) or [online](#).
7. HREC approval is granted on the assumption that all students and early career researchers are adequately supervised by the principal and senior investigators on a project. This supervision would ensure that all privacy concerns are met (including the completion of confidentiality agreements by participating students) and that both students and participants are supported in the conduct of the study in line with the approved research protocol.

Should you have any queries about the HREC's consideration of your project please contact the Executive Officer - (02) 9767-5622. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the [website](#).

Please quote the local reference number at the top of this letter in all correspondence.

Yours sincerely,



Professor David Le Couteur
Chair - Sydney Local Health District Human Research Ethics Committee – CRGH