NEPEAN BLUE MOUNTAINS LOCAL HEALTH DISTRICT HUMAN RESEARCH ETHICS COMMITTEE

CERTIFICATE OF APPROVAL

Friday 18th May 2018

Ms Bernadette Dutton
Professional Educator
Allied Health & Community Programs Directorate
NBMLHD Education and Training Service (ETS)
Nepean Blue Mountain Local Health District
Nepean 2 Building, Nepean Hospital

Dear Ms Dutton,

HREC study reference: HREC/18/NEPEAN/10.
Study title: - *A Pilot Randomised Control Trial to determine the acceptability and feasibility of providing early intervention with the Omo Neurexa shoulder orthosis when compared to usual practice, in reducing the development of Hemiplegic shoulder pain post stroke.*

Your request to undertake the above protocol was considered by the NBMLHD Human Research Ethics Committee (HREC) at its meeting held on the ***30th January 2018.***

On receipt of your responses dated ***26/4/2018*** *to the concerns of the Committee dated* ***14/2/2018,*** *we are satisfied that your protocol meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was* ***APPROVED*** *on* ***the 8th May 2018 to be conducted as a single site study.***

It is the Principal Investigator's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Principle Researcher is required to note the following conditions of approval:

- The coordinating investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project.
- The coordinating investigator will immediately report any protocol deviation / violation, together with details of the procedure put in place to ensure the deviation / violation does not recur.
- The Coordinating Investigator will provide to the HREC in the specified format proposed amendments to the protocol or conduct of the research which may affect the ethical acceptability of the project. Copies of all proposed changes when approved by the HREC must also be provided to the research governance officer.
- The HREC must be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

Nepean Blue Mountains Local Health District
Research Office
Level 5, South Block
ABN 31 910 677 424
PO Box 63, Penrith NSW 2751
Tel (02) 4734 2000
Website www.nbmlhd.health.nsw.gov.au

- The Coordinating Chief Investigator must provide an annual report to the HREC and a final report at completion of the study, in the specified format. HREC approval is granted for a period of 5 years and ongoing approval is contingent upon annual report submission. Annual Reports for all studies should be submitted on the anniversary of the approval date of project. They will be processed and presented to the HREC at the next scheduled meeting. A copy of the Annual / Final Research Report Form can be obtained electronically from the Research Office on request.
- It should be noted that compliance with the ethical guidelines is entirely the responsibility of the investigators.
- The HREC has the discretion to adopt other appropriate mechanism for monitoring depending on the complexity, design and risk perceived, including:
  - Discussion of relevant aspects of the project with investigators at any time.
  - Random inspection of research sites, data or consent
  - Interview with research participants or other formats of feedback from them.
  - Request and review reports from independent agencies such as Data and Safety Monitoring Board.
- For clinical trials using implantable medical devices, the coordinating investigator will confirm to the HREC that a process has been established for tracking participants with consent for the lifetime of the device and will immediately report any device incidents to the Therapeutic Goods Administration (TGA).
- If your research project is an interventional trail please ensure you register your trial onto one of the clinical trial registries, for example. http://www.anzctr.org.au/

The NBMLHD HREC has been accredited by the NSW Ministry of Health as a lead HREC to provide the single ethical and scientific review of proposals to conduct research within the NSW public health system. 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*

SPECIAL CONDITIONS: N/A

Approved Documents:

Documents reviewed and approved at the meeting were:

Document	Version	Date
NEAF Submission code AU/1/C743312	-	-
Protocol	2	20.4.2018
Participant Information Sheet and Consent Form	3	8.5.2018
Motor Assessment Scale	-	-
Tardieu Scale	-	-
TGA Registration Certificate Orthosis - noted	-	-

Approved Sites:

Approval is given for this research project to be conducted at the following sites and campuses:

Insert Site / Sites

- **Nepean Hospital Acute Stroke Unit.**

RESEARCH GOVERNANCE - Site-Specific Assessment (SSA):
SSA authorisation is required at all sites participating in the study. SSA must be authorised at a site before the research project can commence via the Chief Executive or their delegate – the Research Governance Officer.
The completed Site-Specific Assessment Form as well as a copy of this ethics approval letter and all approved documents must be submitted to the Research Governance Officer for authorisation by the Chief Executive or delegate. This applies to each site participating in the research.

Yours Sincerely,

A/Prof Ian Seppelt
Chair, Human Research Ethics Committee
Nepean Blue Mountains LHD

Please quote project number and title in all correspondence