18 July 2017

Dr Heidi Janssen
Stroke Research Team
Hunter Medical Research Institute

Dear Dr Janssen,

Re: S+SLAMTIA: Service change and Supporting Lifestyle and Activity Modification after TIA (17/06/21/4.03)

HNEHREC Reference No: 17/06/21/4.03
NSW HREC Reference No: HREC/17/HNE/235

Thank you for submitting the above application for single ethical review for a multi-centre study. This project was first considered by the Hunter New England Human Research Ethics Committee at its meeting held on **21 June 2017.** This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review. The Committee's Terms of Reference are available from the Hunter New England Local Health District website.

I am pleased to advise, the Hunter New England Human Research Ethics Committee has determined that the above protocol meets the requirements of the *National Statement on Ethical Conduct in Human Research* and following acceptance of the requested clarifications and revised Information Statement and Consent Form by Dr Nicole Gerrand Manager, Research Ethics & Governance, under delegated authority from the Committee, grants ethical approval of the above project.

The *National Statement on Ethical Conduct in Human Research (2007),* which the Committee is obliged to adhere to, include the requirement that the Committee monitors the research protocols it has approved. Ethics Approval will be ongoing subject to the following conditions:

- A report on the progress of the above protocol is to be submitted at 12 monthly intervals. A proforma for the annual report will be sent at the beginning of the month of the anniversary of approval. Your review date is **July 2018.**
- All variations or amendments to this protocol must be forwarded to, and approved by, the Hunter New England Human Research Ethics Committee prior to their implementation.
- A final report must be submitted at the completion of the above protocol, that is, after data analysis has been completed and a final report compiled.
- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
    - Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement:

Hunter New England Research Ethics & Governance Office
Locked Bag No 1
New Lambton NSW 2305
Telephone: (02) 49214950
Email: HNELHD-HREC@hnehealth.nsw.gov.au
http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx

Monitoring and reporting of safety for clinical trials involving therapeutic products May 2009
https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e112_nhmrc_position_statement_monitoring_reporting_safety_clinical_trials.pdf

- Unforeseen events that might affect continued ethical acceptability of the project.

➢ If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand as soon as possible.

The following documentation has been reviewed and approved by the Hunter New England Human Research Ethics Committee:

Document	Version	Date
NEAF [Submission Code: AU/1/524E24]		
Data Collection Timeline	Version 1	31 May 2017
Screening for Eligibility Tool	Version 2	17 July 2017
Participant Information Statement	Version 2	17 July 2017
Participant Consent Form	Version 2	17 July 2017
Participant Consent Form – Outcomes Study	Version 2	17 July 2017
Recruitment, Participant Flow and Data Collection	Version 1	31 May 2017
Participant Case Report Form	Version 1	31 May 2017
Semi-structured Interview Guide	Version 1	31 May 2017

Approval has been granted for this study to take place at the following sites:

- **Community Stroke Service**
- **Hunter Medical Research Institute**

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Should you have any concerns or questions about your research, please contact Dr Gerrand as per the details at the bottom of the page. The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Please quote **17/06/21/4.03** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Ms M Hunter
Chair
Hunter New England Human Research Ethics Committee

Hunter New England Research Ethics & Governance Office
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Email: HNELHD-HREC@hnehealth.nsw.gov.au
http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx