

23 October 2017

Dr Anupam Datta Gupta  
Rehabilitation Physician  
Department of Rehabilitation Medicine  
The Queen Elizabeth Hospital

Dear Dr Gupta,

**Project title:** Efficacy of Botulinum Toxin A on Walking and Quality of Life in Post-Stroke Lower Limb Spasticity - a randomized double blind placebo controlled study.

**HREC reference number:** HREC/17/TQEH/109

**CALHN reference number:** Q20170509

**RE: Ethics Application APPROVAL**

Thank you for submitting the above project for ethical and scientific review. The project was first considered by The Queen Elizabeth Hospital Human Research Ethics Committee (TQEH/LMH/MH) at its meeting held on 10 July 2017, and further responses reviewed at the meeting on 9 October 2017.

The HREC has reviewed all responses, and I am pleased to advise that your protocol has been granted full ethics approval and meets the requirements of the *National Statement on Ethical Conduct in Human Research, incorporating all updates*. The documents reviewed and approved include:

<b>Document</b>	<b>Version</b>	<b>Date</b>
NEAF Application	AU/1/65FD212	18 May 2017
Cover Letter	-	18 May 2017
Protocol	5	23 October 2017
Participant Information Sheet and Consent Form	3	10 October 2017
Spasticity Data Collection Forms	-	-
Letter of Support - Physiotherapy: Adam Govier, Director of Physiotherapy	-	31 August 2017
Letter of Support - Orthotics: Louise Baxter, Director of Orthotics and Prosthetics	-	1 September 2017
Botox TGA Product Information	12	24 September 2015

Site covered by this approval:

- **The Queen Elizabeth Hospital, SA: Dr Anupam Datta Gupta**

HREC approval is valid for **5 years** from **23 October 2017** to **23 October 2022**.

Please quote the **HREC Reference number, HREC/17/TQEH/109** and the **CALHN Reference number, Q20170509** allocated to your study on all future correspondence.

**GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:**

1. For all clinical trials, the study must be registered in a publicly accessible trials registry prior to enrolment of the first participant.
2. This HREC is certified with the NHMRC for National Mutual Acceptance of Single Ethical and Scientific Review of Multi-Centre Clinical Trials. Any study sites that are not listed on this letter are not covered by this ethics approval. Any study-sites that wish to be added must contact the CPI, who must write formally to this HREC requesting the additional study site.

3. Adequate record-keeping is important and must be maintained in accordance with GCP, NHMRC and state and national guidelines. If the project involves signed consent, you should retain the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them in the future if necessary. The duration of record retention for all clinical research data is 15 years.
4. Researchers must notify the HREC of anything which might warrant review of the approval of the study, or which warrant new information being presented to research participants, including:
  - (a) adverse events which warrant protocol change or notification to research participants;
  - (b) changes to the protocol;
  - (c) changes to the safety or efficacy of the investigational product, device or method;
  - (d) premature termination of the study.
5. The Committee must be notified within 72 hours of any Urgent Safety Measures (USMs) occurring at this or any approved sites.
6. Confidentiality of the research participants shall be maintained at all times as required by law.
7. Approval is valid for **5 years** from the date of this letter, after which an extension must be applied for.
8. Annual review reports must be submitted to the HREC, every 12-months on the anniversary of the above approval date. Each site covered by this HREC must submit a report, and it is the responsibility of the Coordinating Principal Investigator to ensure this is provided to the TQEH HREC Executive Officer, within 10 working days on each anniversary of the approval date, using the Annual Review Form available at: <http://www.basilhetzelinstitute.com.au/research/information-for-researchers/human-research-ethics-committee/>
9. The HREC must be advised with a final report or in writing, and a copy of any published material within 30 days of completion of the project.

**You are reminded that this letter constitutes ethical approval only. You must not commence this research project at any site until separate authorisation from the Chief Executive or delegate of that site has been obtained. For any queries, please contact the CALHN Governance Office:**  
[Health.CALHNResearchGovernance@sa.gov.au](mailto:Health.CALHNResearchGovernance@sa.gov.au)

This Committee endorses the NHMRC Guidance on *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (November 2016). <https://www.nhmrc.gov.au/guidelines-publications/eh59>. The Guidance applies to all Clinical trials for safety monitoring and reporting of Investigational Medicinal Products (IMPs) and Investigational Medical Devices (IMDs), approved by this Committee.

This Committee is constituted in accordance with the NHMRC *National Statement on the Ethical Conduct of Human Research* (2007) incorporating all updates.

Should you have any queries about the HREC's consideration of your project, please contact Mrs Heather O'Dea, HREC Executive Officer on 08 8222 6841 or [Health.CALHNResearchEthics@sa.gov.au](mailto:Health.CALHNResearchEthics@sa.gov.au)

The HREC wishes you every success in your research.

Yours sincerely



Professor Richard E Ruffin  
Chairman, Human Research Ethics Committee (TQEH/LMH/MH)

RR:HO

Cc: Site Research Governance Officer