

17 April 2018

Prof Gemma Figtree  
Department of Cardiology  
Acute Services Building, Level 5  
Royal North Shore Hospital  
St Leonards NSW 2065

Dear Gemma,

**NSLHD reference: RESP/18/27**

**Title: Stimulating B3 Adrenergic Receptors to improve clinical outcomes in patients with Peripheral Arterial Disease - STAR-PAD trial**

**HREC reference: HREC/18/HAWKE/50**

Thank you for your letter, dated **6 April 2018**, responding to the Northern Sydney Local Health District HREC's request for additional information/modification for the above project, which was first considered by the HREC at its meeting held on **12 February 2018**. This HREC has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National model for Harmonisation of Multicentre Ethical Review (HoMER). 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*. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the Committee at an Executive meeting on **11 April 2018** has granted ethical and scientific approval of the above **multi centre** project. The HREC were satisfied that this project meets the requirements of the National Statement.

The project is approved to be conducted at:

- **Royal North Shore Hospital**
- **Westmead Hospital**
- **Royal Prince Alfred Hospital**

**You are reminded that this letter constitutes *ETHICAL* and *SCIENTIFIC* approval only. You must not commence this research project at a site until a completed Site Specific Assessment Form/Access Request and associated documentation have been submitted to the site Research Governance Officer and Authorised. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.**

If a new site(s) is to be added please inform the HREC in writing and submit a Site Specific Assessment Form (SSA) to the Research Governance Officer at the new site.

The following documentation has been reviewed and approved by the HREC:

Document	Version	Date
Study Protocol	2.0	6 April 2018
Participant Information Sheet and Consent Form – Master	2.0	6 April 2018
Participant Questionnaire – Walking Impairment	-	-
Participant Questionnaire – SF-36	-	-
Patient Diary	-	-

The Human Research Ethics Application reviewed by the HREC was **HREA AU/1/42B3313**.

Please note that it is the responsibility of the Sponsor to submit the Clinical Trial Notification (CTN) to the Therapeutic Goods Administration (TGA) online. The Research Office recommends that CTN submission is completed only once HREC approval *and* site governance authorisation are granted.

Please note the following conditions of approval:

- HREC approval is valid for **5 years** from the date of approval and expires on **11 April 2023**. The Co-ordinating Investigator is required to notify the HREC 6 months prior to this date if the project is expected to extend beyond the original approval date at which time the HREC will advise of the requirements for ongoing approval of the study.
- The Co-ordinating Investigator will provide an annual progress report to the Institution beginning in **August 2018** as well as a final study report at the completion of the project using the template available on the Research Office website. An annual report is due **every year on 30 August**.
- The Co-ordinating 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 and any complaints made by study participants regarding the conduct of the study.
- Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review, in the specified format.
- The HREC will be notified, giving reasons, if the project is discontinued before the expected date of completion.
- Investigators holding an academic appointment (including conjoint appointments) and students undertaking a project as part of a university course are advised to contact the relevant university HREC regarding any additional requirements for the project.

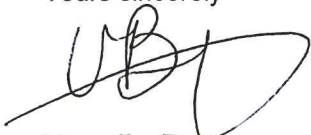
Please note it is the responsibility of the sponsor or the co-ordinating investigator of the project to register this study on a publicly available online registry (eg Australian New Zealand Clinical Trial Registry [www.anzctr.org.au](http://www.anzctr.org.au)) if applicable.

Should you have any queries about your project please contact the Research Office, Tel: 9926 4590, email [NSLHD-Research@health.nsw.gov.au](mailto:NSLHD-Research@health.nsw.gov.au).

Please quote **NSLHD reference RESP/18/27** in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely



**Veronika Burgess**  
*Research Ethics Officer*  
NORTHERN SYDNEY LOCAL HEALTH DISTRICT

cc. Luisa Osorio

RESD/18/3068