Health
South Eastern Sydney
Local Health District

HUMAN RESEARCH ETHICS COMMITTEE
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27 September 2018

Dr Charlotte Atkinson
Level 4 Pitney Building
St George Hospital
KOGARAH NSW 2217

Dear Dr Atkinson

HREC ref no: 17/278 (HREC/18/POWH/325)
Project title: Randomised Controlled Trial of Prophylactic Pregabalin in Head and Neck Cancer Patients treated with Radical Radiotherapy

Thank you for submitting the above application for ethical and scientific review and for your correspondence dated **13 September 2018** to the Executive Officer responding to questions which arose at the Executive Committee meeting on **06 September 2018** Authority to grant final approval was delegated to the Executive Officer. I am pleased to advise that that the proposal meets the requirements of the National Statement on Ethical Conduct of Human Research and ethics approval has been given for the following:

- NEAF submission AU/1/A7F637 dated 07/06/2018
- Protocol V3.2 dated 22 Aug 2018
- PIS&CF V1.4 dated Sept 2018
- CRF V4.1 dated 21 Aug 2018
- Radiation Safety Report, St George (no additional radiation) 09 July 2018
- Radiotherapy Planning Guidelines V1.0 dated 21 Aug 2018
- Weekly Medication Chart
- Opioid dose Equivalence (FPM, ANZCA) December 2014

Ethics approval is valid for the following site(s):

- St George Hospital

Conditions of approval

1. This approval is valid for 5 years from the date of this letter.
2. Annual reports must be provided on the anniversary of approval.
3. A final report must be provided at the completion of the project.

4. Proposed changes to the research protocol, conduct of the research, or length of approval will be provided to the Committee.
5. The Principal Investigator will immediately report matters which might warrant review of ethical approval, including unforeseen events which might affect the ethical acceptability of the project and any complaints made by study participants.

It is the responsibility of the sponsor or the principal (or co-ordinating) investigator of the project to register this study on a publicly available online registry (eg Australian New Zealand Clinical Trials Registry www.anzctr.org.au).

For Public Health Sites: You are reminded that this letter constitutes ethics approval only. You must not commence this research project until you have submitted your Site Specific Assessment (SSA) to the Research Governance Officer of the appropriate institution and have received a letter of authorisation from the General Manager or Chief Executive of that institution.

Should you have any queries, please contact the Research Support Office on (02) 9382 3587. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Research Support Office website: https://www.seslhd.health.nsw.gov.au/services-clinics/directory/seslhd-research

Please quote **17/278** in all correspondence.

We wish you every success in your research.

Yours sincerely

Andrew Bohlken
Executive Officer, Human Research Ethics Committee

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*, NHMRC and Universities Australia *Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.