



HUMAN RESEARCH ETHICS COMMITTEE - NORTHERN SECTOR

Room G71 East Wing
Edmund Blacket Building
Prince of Wales Hospital
RANDWICK NSW 2031
Tel: 02 9382 3587 Fax: 02 9382 2813
www.sesiahs.health.nsw.gov.au/Research_Support/NHN/

29 April 2011

Dr Arun Krishnan
Institute of Neurological Sciences
Prince of Wales Hospital
High St
RANDWICK NSW 2031


Dear Dr Krishnan

HREC ref no: 10/236

Project title: NEU-HORIZONS: The neuroprotection and therapeutic use of Riluzole for the prevention of oxaliplatin neurotoxicity study.

Thank you for submitting the above application for ethical and scientific review. The application was first considered by the Human Research Ethics Committee (HREC) at a meeting on 22 February 2011 and subsequently on 5 April 2011 at which further information was requested.

At that meeting the Committee requested that the investigator provide further information/clarification or modification delegating authority to approve the application to the Executive Officer upon receipt of a satisfactory response. The requested information and modifications were received with your correspondence dated 14 April 2011.

I am pleased to advise that ethical approval has been granted for this project to be conducted at the Prince of Wales Hospital.

The following documentation has been approved:

- NEAF, submission code AU/1/1942808
- Study protocol, version 2, dated 14 April 2011
- Participant Information Statement and Consent Form, version 3, dated 13 April 2011
- Participant Information Statement and Consent Form – Tissue banking Genetic Repositories Australia, version 3, dated 14 April 2011

Questionnaires:

- FACT/GOG-Ntx (4 item), not dated
- Total Neuropathy Score – Clinical, not dated

Case Report Forms:

- Baseline visit, version 1, dated 13 December 2010
- Regular visits, version 1, dated 13 December 2010

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.

Optional 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 NSW Public Health sites only: You are reminded that this letter constitutes ethical 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: http://www.sesiahs.health.nsw.gov.au/Research_Support/NHN/.

Please quote **HREC ref no 10/236** in all correspondence.

We wish you every success in your research.

Yours sincerely



Deborah Adrian
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 Research Involving Humans* (2007), NHMRC and Universities Australia's *Guidelines on the Ethical Conduct of Research* (2007) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

South Eastern Sydney Local Health Network
Network Executive Unit
Locked Mail Bag 21 TAREN POINT NSW 2229
Tel: (02) 9540 7756 Fax: (02) 9540 8757
www.sesiahs.health.nsw.gov.au
ABN 70 442 041 439