



11 April 2013

A/Professor Mark Parsons  
Department of Neurology  
John Hunter Hospital

Dear Professor Parsons,

**Re: A phase III multicentre, prospective, randomised open-label blinded endpoint (PROBE) study: Tenecteplase versus Alteplase for Stroke Thrombolysis Evaluation (TASTE) (13/02/20/3.04)**

**HNEHREC Reference No: 13/02/20/3.04**  
**NSW HREC Reference No: HREC/13/HNE/23**

Thank you for submitting the above protocol 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 **20 February 2013**. 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: [http://www.hnehealth.nsw.gov.au/Human\\_Research\\_Ethics](http://www.hnehealth.nsw.gov.au/Human_Research_Ethics).

I am pleased to advise that following acceptance under delegated authority of the requested clarifications and revised Information Statements and Consent Forms by Dr Nicole Gerrand Manager, Research Ethics & Governance, the Hunter New England Human Research Ethics Committee has granted ethical approval of the above project.

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

- For the HMRI2012101 Protocol (Version 2 dated 11 December 2012);
- For the Master Participant Information Sheet and Consent Form (Version 3.0 dated 9 April 2013);
- For the Master Participant Information Sheet and Consent Form – (Short Version) (Version 3.0 dated 9 April 2013);
- For the Master Person Responsible Information Sheet and Consent Form (Version 3.0 dated 9 April 2013); and
- For the Master Person Responsible Information Sheet and Consent Form – (Short Version) (Version 3.0 dated 9 April 2013)

**Hunter New England Research Ethics & Governance Unit**

(Locked Bag No 1)

(New Lambton NSW 2305)

Telephone (02) 49214 950 Facsimile (02) 49214 818

Email: [hnehrec@hnehealth.nsw.gov.au](mailto:hnehrec@hnehealth.nsw.gov.au)

[http://www.hnehealth.nsw.gov.au/research\\_ethics\\_and\\_governance\\_unit](http://www.hnehealth.nsw.gov.au/research_ethics_and_governance_unit)

