NSW GOVERNMENT Health
Hunter New England
Local Health District

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.

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)
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Telephone (02) 49214 950 Facsimile (02) 49214 818
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For the protocol: **Tenecteplase versus Alteplase for Stroke Thrombolysis Evaluation (TASTE) Trial [Protocol No. HMRI2012101 Version 2 dated 11 December 2012]**

Approval has been granted for this study to take place at the following sites:

- **John Hunter Hospital, New Lambton NSW**
- **Gosford Hospital, Gosford NSW**
- **Liverpool Hospital, Liverpool NSW**
- **Royal North Shore Hospital, St Leonards NSW**
- **Royal Prince Alfred Hospital, Camperdown NSW**
- **St Vincent's Hospital, Darlinghurst NSW**
- **Westmead Hospital, Westmead NSW**
- **Gold Coast Hospital, Southport QLD**
- **Nambour General Hospital, QLD**
- **Royal Brisbane & Women's Hospital, Herston QLD**
- **Box Hill Hospital, Box Hill VIC**
- **Monash Medical Centre, Clayton VIC**
- **Royal Melbourne Hospital, Parkville VIC**
- **The Austin Hospital, Heidelberg VIC**
- **The Western Hospital, Footscray VIC**

Approval from the Hunter New England Human Research Ethics Committee for the above protocol is given for a maximum of **5** years from the date of this letter, after which a renewal application will be required if the protocol has not been completed.

The *National Statement on Ethical Conduct in Human Research (2007),* which the Committee is obliged to adhere to, include the requirement that the committee monitors the research protocols it has approved. In order for the Committee to fulfil this function, it requires:

- A report of the progress of the above protocol be submitted at 12 monthly intervals. Your review date is **April 2014.** A proforma for the annual report will be sent two weeks prior to the due date.

- A final report must be submitted at the completion of the above protocol, that is, after data analysis has been completed and a final report compiled. A proforma for the final report will be sent two weeks prior to the due date.

- All variations or amendments to this protocol, including amendments to the Information Sheet and Consent Form, must be forwarded to and approved by the Hunter New England Human Research Ethics Committee prior to their implementation.

- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:

    - any serious or unexpected adverse events

        - Adverse events, however minor, must be recorded as observed by the Investigator or as volunteered by a participant in this protocol. Full details will be documented, whether or not the Investigator or his deputies considers the event to be related to the trial substance or procedure. These do not need to be reported to the Hunter New England Human Research Ethics Committee

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- Serious adverse events that occur during the study or within six months of completion of the trial at your site should be reported to the Manager, Research Ethics & Governance, of the Hunter New England Human Research Ethics Committee as soon as possible and at the latest within 72 hours.

- All other safety reporting should be in accordance with the NHMRC's Safety Monitoring Position Statement – May 2009 available at http://www.nhmrc.gov.au/health_ethics/hrecs/reference/_files/090609_nhmrc_position_statement.pdf

- Serious adverse events are defined as:

  - Causing death, life threatening or serious disability.
  - Cause or prolong hospitalisation.
  - Overdoses, cancers, congenital abnormalities whether judged to be caused by the investigational agent or new procedure or not.

- Unforeseen events that might affect continued ethical acceptability of the project.

- If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand, as soon as possible.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Should you have any concerns or questions about your research, please contact Dr Gerrand as per the details at the bottom of the page. The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Please quote **13/02/20/3.02** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Dr Ron Owens
Deputy Chair
Hunter New England Human Research Ethics Committee

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