



Human Research Ethics Committee (TQEH/LMH/MH)

Basil Hetzel Institute DX465101
The Queen Elizabeth Hospital
28 Woodville Road
Woodville South SA 5011
Telephone: 08 8222 6841
Email: qeh.ethics@health.sa.gov.au

02 April 2014

Dr Jim Jannes
Stroke Unit
The Queen Elizabeth Hospital
28 Woodville Road
Woodville South SA 5011

Dear Dr Jannes

HREC reference number: HREC/13/TQEHLMH/303

Project title: Tenecteplase versus Alteplase for Stroke Thrombolysis Evaluation (TASTE) Trial

RE: HREC/13/TQEHLMH/303 - Ethics Application Approval

Thank you for submitting additional information received on 24 January 2014 in relation to the above project for ethical and scientific review.

The Chairman has reviewed your response, and I am pleased to advise that your protocol has been granted full ethics approval and meets the requirements of the *National Statement on Ethical Conduct in Human Research*. The documents reviewed and approved include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Application: NEAF: <ul style="list-style-type: none"> • Lyell McEwin Hospital, SA • The Queen Elizabeth Hospital, SA • Royal Adelaide Hospital, SA • Flinders Medical Centre, SA 	-	04 November 2013
Covering Letter: Submission	-	13 November 2013
Protocol: HMRI2012101 TASTE	4	17 September 2013
Person Responsible Information Sheet and Consent Form: short version	SA Master v1.1	17 January 2014
Person Responsible Information Sheet and Consent Form: long version	SA Master v1.1	17 January 2014
Participant Information Sheet and Consent Form: long version	SA Master v1.1	17 January 2014
Participant Information Sheet and Consent Form: short version	SA Master v1.1	17 January 2014
Response to Request for Further Information		17 January 2014

HREC approval is valid from **02 April 2014 to 02 April 2015**.

Please note the following conditions of approval:

1. This HREC is certified with the NHMRC for National Mutual Acceptance of Single Ethical and Scientific Review of Multi-centre Clinical Trials. Therefore this HREC can act as a 'lead HREC' for the purpose of this ethics approval. Any study sites that are not listed on this letter are not covered by this ethics approval. Any study-sites that

- wish to be added must contact the CPI, who must write formally to this HREC requesting the additional study site and a separate formal letter will be issued.
2. Researchers are required to immediately report to this HREC anything which might warrant review of ethical approval of the protocol, including:
 - a. serious or unexpected adverse effects on participants;
 - b. proposed changes in the protocol; and
 - c. unforeseen events that might affect continued ethical acceptability of the project.
 3. Protocols are approved for up to twelve months only and a report is required at the end of the study or 12 month period. Extensions will not be granted without a report to the Committee.
 4. Confidentiality of the research subjects shall be maintained at all times as required by law.
 5. All research subjects shall be provided with a Participant Information Sheet and Consent Form, unless otherwise approved by the Committee.
 6. The Participant Information Sheet and Consent Form shall be printed on the relevant site letterhead stating the contact details for the researchers.
 7. A report and a copy of any published material should be forwarded to the Committee at the completion of the project.

This Committee is constituted in accordance with the NHMRC's *National Statement on the Ethical Conduct of Human Research* (2007).

Should you have any queries about the HREC's consideration of your project please contact the HREC Executive Officer on 08 8222 6841 or geh.ethics@health.sa.gov.au

You are reminded that this letter constitutes ethical approval only. You cannot commence this project until you receive site authorisation from the Chief Executive Officer or delegate, even if ethics approval is received.

To obtain site authorisation, a separate Site Specific Assessment (SSA) application should be made to each site involved in the study, through the Site's Research Governance Officer. For more information, please visit: <http://www.basilhetzelinstitute.com.au/research/research-ethics-governance/governance-site-specific-assessments-ssa->

The HREC wishes you every success in your research.

Yours sincerely



A/Professor Timothy Mathew
Chairman, Human Research Ethics Committee (TQEH/LMH/MH)
TM:mk