

East Midlands - Nottingham 2 Research Ethics Committee

Equinox House
City Link
Nottingham
NG2 4LA

Tel: 02071048016

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

31 March 2022

Prof Nikola Sprigg
Chief Investigator/Professor Stroke Medicine
University of Nottingham
AUI Mental Health and Clinical Neurosciences
Queens Medical Centre
Derby Road, Nottingham
NG7 2UH

Dear Prof Sprigg

Study title:	Tranexamic acid for Hyperacute Spontaneous Intracerebral Haemorrhage (TICH-3)
REC reference:	21/EM/0243
Protocol number:	21022
EudraCT number:	2021-001050-62
Amendment number:	SA02/2022/21/02
Amendment date:	21 February 2022
IRAS project ID:	297457

The above amendment was reviewed at the meeting of the Sub-Committee held on 21 March 2022 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [297457_SA02.2022.21.02]	SA02	17 March 2022
Cover Letter [SA02 Amendment Cover Letter]	1.0	21 February 2022
Other [TICH-3 SWAT Transcript]	1.0	21 February 2022
Validated questionnaire [Day 180 Follow Up Form]	1.1	31 January 2022

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004 and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

IRAS Project ID - 297457:

Please quote this number on all correspondence

Yours sincerely

A handwritten signature in black ink, appearing to read 'Bernadette Roberts', with the initials 'P.P.' written above it.

Ms Bernadette Roberts
Chair

E-mail: nottingham2.rec@hra.nhs.uk

Enclosures: List of names and professions of members who took part in the review

Copy to: Ms Angela Shone

East Midlands - Nottingham 2 Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 21 March 2022

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Carla Richardson	Senior Trial Manager	Yes	
Ms Bernadette Roberts	Retired Finance Manager	Yes	Chair

Also, in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Noorisha Rahman	Approvals Administrator