

**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 October 2022

Professor 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 Professor, Sprigg

<b>Study title:</b>	<b>Tranexamic acid for Hyperacute Spontaneous Intracerebral Haemorrhage (TICH-3)</b>
<b>REC reference:</b>	<b>21/EM/0243</b>
<b>Protocol number:</b>	<b>21022</b>
<b>EudraCT number:</b>	<b>2021-001050-62</b>
<b>Amendment number:</b>	<b>SA04_12-09-22</b>
<b>Amendment date:</b>	<b>12 September 2022</b>
<b>IRAS project ID:</b>	<b>297457</b>

The above amendment was reviewed at the meeting of the Sub-Committee held on 31 October 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 [Completed Amendment Tool SA04]	SA04_12-09-22	12 September 2022
Cover Letter [Cover Letter Protocol Amendment]	1.0	07 October 2022
Other [Purchase Order MHRA]	1.0	22 September 2022
Research protocol or project proposal [TICH-3 protocol draft V2 UPDATED for submission 07.10 version control table_clean]	2.0	07 October 2022
Research protocol or project proposal [TICH-3 protocol draft V2 UPDATED for submission tracked changes 07.10 version control table]	2.0	07 October 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.

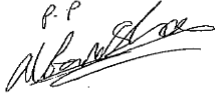
## HRA Learning

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](mailto:nottingham2.rec@hra.nhs.uk)

## East Midlands - Nottingham 2 Research Ethics Committee

### Attendance at Sub-Committee of the REC meeting on 31 October 2022

#### Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Leanne Morgan	Grants Development Manager	Yes	
Ms Bernadette Roberts	Retired Finance Manager	Yes	Chair

#### Also, in attendance:

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