

East Midlands - Nottingham 2 Research Ethics Committee

Equinox House  
City Link  
Nottingham  
NG2 4LA

Tel: 02071048248

**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.**

17 December 2021

Ms Angela Shone  
University of Nottingham  
Head of Research Governance, Research and Innovation.  
East Atrium, Jubilee Conference Centre, Triumph Road  
NG8 1DH

Dear Ms Shone,

**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:** SA01/2021/22/11  
**Amendment date:** 22 November 2021  
**IRAS project ID:** 297457

The above amendment was reviewed 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:

Document	Version	Date
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Completed Amendment Tool [Amendment Tool]	SA01	22 November 2021
IRAS Application Form [IRAS Application Form Signed]		25 October 2021
Summary CV for Chief Investigator (CI) [Nikola Sprigg CV]	1.0	17 January 2019

## 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/>

<b>IRAS Project ID - 297457:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely  
pp.



Lucie Conway

**Mr Jon Merrills**

**Chair**

E-mail: [nottingham2.rec@hra.nhs.uk](mailto:nottingham2.rec@hra.nhs.uk)

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

*Copy to: Prof Nikola Sprigg, University of Nottingham*

**East Midlands - Nottingham 2 Research Ethics Committee**

**Attendance at Sub-Committee of the REC meeting on 13 December 2021 via correspondence.**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr Jon Merrills (Chair)	Barrister/Pharmacist	Yes	
Mrs Leanne Morgan	Grants Development Manager	Yes	

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Lucie Conway	Approvals Administrator