

East Midlands - Nottingham 2 Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

24 October 2019

Dr Nikola Sprigg
Clinical Associate Professor
University of Nottingham
Clinical Sciences Building, City Hospital Campus
Hucknall Road
Nottingham
NG5 1PB

Dear Dr Sprigg

Study title:	Desmopressin for reversal of Antiplatelet drugs in Stroke due to Haemorrhage (DASH)
REC reference:	18/EM/0184
Protocol number:	18040
EudraCT number:	2018-001904-12
Amendment number:	SA/03/19
Amendment date:	13 September 2019
IRAS project ID:	233744

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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper		16 September 2019
GP/consultant information sheets or letters	2.0	26 August 2019
Non-validated questionnaire [90 Day Follow-up Postal Copy]	1.1	27 August 2019
Notice of Substantial Amendment (CTIMP)	SA/03/19	13 September 2019
Participant information sheet (PIS)	2.0	26 August 2019
Participant information sheet (PIS) [Nominee]	2.0	26 August 2019
Research protocol or project proposal	2.0	26 August 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.

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/>

18/EM/0184:	Please quote this number on all correspondence
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Yours sincerely

pp. 

Ms Bernadette Roberts
Chair

E-mail: NRESCCommittee.EastMidlands-Nottingham2@nhs.net

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 07 October 2019

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Ms Bernadette Roberts	Retired Finance Manager	Yes	Chair
Dr Ian Ross	Retired Consultant Physician	Yes	