

East Midlands - Nottingham 2 Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

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.

21 February 2019

Diane Havard
Senior Clinical Trials Manager
Stroke Division of Clinical Neuroscience
School of Medicine
Faculty of Medicine and Health Sciences
Room A07, Clinical Sciences Building
University of Nottingham
City Hospital Campus
Hucknall Road
Nottingham
NG5 1PB

Dear Diane,

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/01/19 and SA/02/19
Amendment date:	31 January 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		29 January 2019
Notice of Substantial Amendment (CTIMP)	SA/01/19 and SA/02/19	31 January 2019
Other [Day 90 follow Up Form - Postal version]	1.0	
Other [Jane Sword CV]		13 November 2017
Other [Jane Sword GCP]		15 November 2015

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.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

18/EM/0184:

Please quote this number on all correspondence

Yours sincerely

pp. 

Ms Bernadette Roberts
Chair

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

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

*Copy to: Dr Maria Koufali, Nottingham University Hospitals NHS Trust
Dr Nikola Sprigg, University of Nottingham
Miss Angela Shone*

East Midlands - Nottingham 2 Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 11 February 2019

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Ms Bernadette Roberts	Retired Finance Manager	Yes	Chair
Dr John Shaw	Retired Patent Licensing Manager	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Joanne O'Neil	REC Assistant