

Partner Organisations:

Health Research Authority, England

NHS Research Scotland

HSC Research & Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England

NISCHR Permissions Co-ordinating Unit, Wales

Notification of Non-Substantial/Minor Amendments(s) for NHS Studies

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.

If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

Instructions for using this template

- For guidance on amendments refer to <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/>
- This template should be completed by the CI and optionally authorised by Sponsor, if required by sponsor guidelines.
- This form should be submitted according to the instructions provided for NHS/HSC R&D at <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/>. If you do not submit your notification in accordance with these instructions then processing of your submission may be significantly delayed.

1. Study Information

Full title of study:	Desmopressin for reversal of Anti-platelet drugs in Stroke due to Haemorrhage
IRAS Project ID:	233744
Sponsor Amendment Notification number:	MA/05/20
Sponsor Amendment Notification date:	06/02/20
Details of Chief Investigator:	
Name [first name and surname]	Professor Nikola Sprigg
Address:	Stroke, Clinical Sciences Building City Hospital Campus, Hucknall Road, Nottingham
Postcode:	NG5 1PB
Contact telephone number:	0115 823 1765
Email address:	Nikola.sprigg@nottingham.ac.uk
Details of Lead Sponsor:	
Name:	Angela Shone
Contact email address:	sponsor@nottingham.ac.uk
Details of Lead Nation:	
Name of lead nation <i>delete as appropriate</i>	England
If England led is the study going through CSP? <i>delete as appropriate</i>	No
Name of lead R&D office:	Nottingham

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2. Summary of amendment(s)

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No.	Brief description of amendment <i>(please enter each separate amendment in a new row)</i>	Amendment applies to <i>(delete/ list as appropriate)</i>		List relevant supporting document(s), including version numbers <i>(please ensure all referenced supporting documents are submitted with this form)</i>		R&D category of amendment <i>(category A, B, C) For office use only</i>
		Nation	Sites	Document	Version	
1	Trial has received a funded extension. New dates: End of recruitment – 30 th June 2020 End of Follow up – 30 th Sept 2020	England Scotland	All sites All sites	N/A	N/A	
2						
3						
4						
5						

[Add further rows as required]

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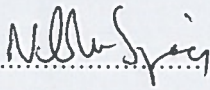
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3. Declaration(s)

Declaration by Chief Investigator

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment(s) to be implemented.

Signature of Chief Investigator: 

Print name:NIKOLA JORGIC.....

Date: 11. FEB 2020

Optional Declaration by the Sponsor's Representative (as per Sponsor Guidelines)

The sponsor of an approved study is responsible for all amendments made during its conduct.

The person authorising the declaration should be authorised to do so. There is no requirement for a particular level of seniority; the sponsor's rules on delegated authority should be adhered to.

- I confirm the sponsor's support for the amendment(s) in this notification.

Signature of sponsor's representative:

Print name:.....

Post:

Organisation:.....

Date:.....

