

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:	Intraoperative Hypotension in Elder Patients: Observational Study of Intraoperative Hypotension in Elder Patients in UK Hospitals (iHypE)
IRAS Project ID:	186097
Sponsor Amendment Notification number:	
Sponsor Amendment Notification date:	
Details of Chief Investigator:	
Name [first name and surname]	Dr Daniel Martin
Address:	Royal Free London NHS Foundation Trust Department of Anaesthesia Royal Free Hospital London
Postcode:	NW3 2QG
Contact telephone number:	07801444428
Email address:	Daniel.martin@ucl.ac.uk
Details of Lead Sponsor:	
Name:	Cameron Berg
Contact email address:	Cameron.berg@uclh.NHS.uk randd@uclh.NHS.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>	Yes
Name of lead R&D office:	University College London Hospitals/ University College London Joint Research Office. randd@uclh.NHS.uk

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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)</i> <i>For office use only</i>
		Nation	Sites	Document	Version	
1	Inclusion of new study sites:	England	<ul style="list-style-type: none"> • George Eliot Hospital NHS Trust • Sherwood Forest Hospitals NHS Foundation Trust • Norfolk and Norwich University Hospital NHS Foundation Trust • West Suffolk NHS Foundation Trust • Queen Elizabeth Hospital Kings Lynn NHS Trust • Southend University Hospital NHS Foundation Trust • Mid Essex Hospital Services NHS Trust • Bedford Hospital NHS Trust • Luton and Dunstable University Hospital NHS Foundation Trust • Peterborough & Stamford Hospitals NHS Foundation Trust • Ipswich Hospital NHS Trust • Hinchingsbrooke Health Care NHS Trust • Cambridge University Hospitals NHS Foundation Trust • James Paget University Hospitals NHS Foundation Trust • Basildon and Thurrock University Hospitals NHS Foundation Trust • Papworth Hospital NHS Foundation Trust • University Hospitals of Coventry and Warwickshire NHS Trust • South Warwickshire NHS Foundation Trust 	N/A	N/A	

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			<ul style="list-style-type: none"> • Queen Victoria Hospital NHS Foundation Trust • Harrogate & District NHS Foundation Trust • Rotherham NHS Foundation Trust 			
		Scotland	<ul style="list-style-type: none"> • NHS Tayside, Ninewells Hospital • NHS Tayside, Perth Royal Infirmary • NHS Highland, Raigmore Hospital • NHS Grampian, Aberdeen Royal Infirmary 			
2	Change of principal investigator at Stockport NHS Foundation Trust: <ul style="list-style-type: none"> • From Dr Sarah Wood To Dr Matthew Jackson 	England	<ul style="list-style-type: none"> • Stockport NHS Foundation Trust 	N/A	N/A	
3	Change of principal investigator at Pennine Acute Hospitals NHS Trust: <ul style="list-style-type: none"> • From Dr Bhaskar Saha To Dr Joanne Humphreys 	England	<ul style="list-style-type: none"> • Pennine Acute Hospitals NHS Trust 	N/A	N/A	
4	Extension of study period beyond that specified on application. <ul style="list-style-type: none"> • Locally determined 48 hour recruitment period within a 2 week window (21/11/16 – 2/12/16). Extend to 10 week window (21/11/16 – 31/01/16). • Reason: to enable local sites to complete the R&D processes. 	England, Scotland & Wales	All sites	Protocol	5.4	

[Add further rows as required]

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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: Dr Daniel Martin

Date: 30/10/2016

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:.....