

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 (please enter each separate amendment in a new row)	Amendment applies to (delete/ list as appropriate)		List relevant supporting document(s), including version numbers (please ensure all referenced supporting documents are submitted with this form)		R&D category of amendment (category A, B, C) For office use only
		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:.....