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 <u>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/</u>. 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:	Improving perioperative care through the use of quality data: Patient Study of the Perioperative Quality
	Improvement Programme
IRAS Project ID:	215928
Sponsor Amendment Notification number:	13
Sponsor Amendment Notification date:	24.05.19
Details of Chief Investigator:	
Name [first name and surname]	Professor Suneetha Ramani Moonesinghe
Address:	Professor SR Moonesinghe
	Centre for Perioperative Medicine
	Department for Targeted Intervention
	Division of Surgery and Interventional Science
	University College London
	Charles Bell House
	43-47 Foley Street
	London
Postcode:	W1W 7TS
Contact telephone number:	07956620717
Email address:	ramani.moonesinghe@nhs.net

Details of Lead Sponsor:

Partner Organisations:	
Health Research Authority, England	NIHR Clinical Research Network, England
NHS Research Scotland	NISCHR Permissions Co-ordinating Unit, Wales
HSC Research & Development, Public Hea	Ith Agency, Northern Ireland
Name:	Suzanne Emerton
Contact email address:	uclh.randd@nhs.net
Details of Lead Nation:	
Name of lead nation	England
delete as appropriate	
If England led is the study going	Yes
through CSP?	
delete as appropriate	
Name of lead R&D office:	Joint Research Office, UCL, London, WC1 E6BT

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	Change of PI at Royal Devon and Exeter Hospital – Dr Kat Haynes will be taking over from Dr Bruce McCormick	England	Royal Devon and Exeter			
	Change of PI at Milton Keynes University Hospital – named PI will be Dr Richard Stewart instead of Dr Graziana Massolini		Milton Keynes University Hospital			
	Change of PI at Medway Maritime Hospital – Dr Caris Grimes will be taking over from Dr Priya Krishnan		Medway Maritime Hospital			
2	Addition of new sites: George Eliot Hospital NHS Trust East Cheshire NHS Trust Salisbury NHS Foundation Trust Betsi Cadwaladr University Health Board Liverpool Women's NHS FT Mid Cheshire Hospitals NHS Foundation Trust Croydon University Hospital Trust Lewisham and Greenwich NHS Trust Wrightington, Wigan and Leigh NHS Foundation Trust Luton and Dunstable University Hospital NHS Foundation Trust	England and Wales				

			work, England linating Unit, Wales			
3	Trust name changes of existing sites Cwm Taf Morgannwg University Health Board	England and Wales				
	Swansea Bay University Health Board South Tyneside and Sunderland NHS Foundation					
	Trust Hull University Teaching Hospitals NHS Trust					
4	Amended version of the Patient Participation Invitation Letter for use at Manchester Royal Infirmary only	England	Manchester Royal Infirmary (MRI)	MRI Patient Participation Invitation Letter	07.04.2019	
			(PQIP Patient Participation Invitation Letter (already ethically	V3. 24.04.2017	
				approved – for comparison only)		

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.

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Signature of Chief Investigator:				
Print name:		SR MOONESINGHE		
Date:	24.05.2019			

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:....