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:	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:	
Sponsor Amendment Notification date:	02/02/2017
Details of Chief Investigator:	
Name [first name and surname]	Dr Suneetha Ramani Moonesinghe
Address:	Anaesthetics Department, Podium 3, Maple Link corridor, University College Hospital 235 Euston Road
Postcode:	NW1 2BU
Contact telephone number:	07956620717
Email address:	ramani.moonesinghe@nhs.net
Details of Lead Sponsor:	
Name:	Suzanne Emerton
Contact email address:	randd@uclh.nhs.uk
Details of Lead Nation:	
Name of lead nation *delete as appropriate*	England
If England led is the study going through CSP? *delete as appropriate*	Yes
Name of lead R&D office:	Joint Research Office, UCL, London, WC1 E6BT

Partner Organisations:
Health Research Authority, England NIHR Clinical Research Network, England
NHS Research Scotland NISCHR Permissions Co-ordinating Unit, Wales
HSC Research & Development, Public Health Agency, Northern Ireland

2. Summary of amendment(s)

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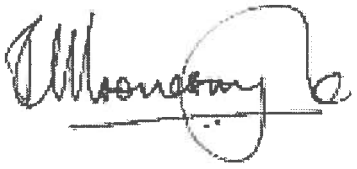
No.	Brief description of amendment *(please enter each separate amendment in a new row)*	Amendment applies to *(delete/ list as appropriate)*		List relevant supporting document(s), including version numbers *(please ensure all referenced supporting documents are submitted with this form)*		R&D category of amendment *(category A, B, C) For office use only*
		Nation	**Sites**	**Document**	**Version**	
1	Minor amendment to Patient Information Sheet and patient consent form to explicitly mention participant data being linked to NHS and governmental databases	England	All sites or list affected sites	PQIP Patient Study PIS PQIP Patient Study Consent Form	v0.7 300117 v0.9 060117	
		Northern Ireland	All sites or list affected sites			
		Scotland	All sites or list affected sites			
		Wales	All sites or list affected sites			
2	Addition of extra sites to Part C of IRAS form: 1. Derby Teaching Hospitals NHS Foundation Trust 2. Nottingham University Hospitals NHS Trust 3. Royal Cornwall Hospitals NHS Trust 4. Stockport NHS Foundation Trust 5. University Hospitals of Morecambe Bay NHS Foundation Trust 6. Cardiff & Vale University Health Board 7. CHESTERFIELD ROYAL HOSPITAL NHS FOUNDATION TRUST 8. James Paget University Hospital NHS Foundation Trust 9. Royal Wolverhampton NHS Trust.	England – Listed sites				

[Add further rows as required]

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: SR MOONESINGHE .....

Date: 02/02/2017

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: DAVID WILSON

Post: UCL SPONSOR REPRESENTATIVE

Organisation: UCL

Date: 07/02/2017