### 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: | 01/12/2016 |
| **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 |

1. **Summary of amendment(s)**

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.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **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 | Protocol amendments as follows:  Minor amendment to study end date – clarification that end will be at 4 years or when recruitment target has been reached, whichever occurs later (p3 study summary and p9) | England | All sites or list affected sites | Protocol v1.5 28112016 | 1.5 |  |
| 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:  Ashford & St Peter's Hospitals NHS Foundation Trust  Burton Hospitals NHS Foundation Trust  Chelsea and Westminster Hospital NHS Foundation Trust  East Sussex Healthcare Trust  Frimley Health NHS Foundation Trust  Frimley Health NHS Foundation Trust  Guy's and St Thomas' NHS Foundation Trust  Hampshire Hospitals NHS Foundation Trust  Nottingham University Hospitals NHS Trust  Oxford University Hospitals NHS Foundation Trust  Pennine Acute Hospitals NHS Trust  Surrey and Sussex Healthcare NHS Trust  Tameside and Glossop Integrated Care NHS Foundation Trust  West Hertfordshire Hospitals NHS Trust  Western Sussex Hospitals NHS Foundation Trust  Wye Valley NHS Trust  Sherwood Forest Hospitals NHS Foundation Trust  University Hospital Birmingham NHS Foundation Trust  NHS Lanarkshire  NHS Highland | England | Listed sites |  |  |  |
| Scotland | Listed sites |
| 3 | Change of Chief Investigator’s email address to ramani.moonesinghe@nhs.net |  | |  |  |  |
| 4 |  |  | |  |  |  |
| 5 |  |  | |  |  |  |

**[Add further rows as required]**

1. **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:* 30 NOVEMBER 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:*……………………………………. |