### 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: | Open, multi-centre, randomised controlled trial of cardiac output-guided fluid therapy with low dose inotrope infusion compared to usual care in patients undergoing major elective gastrointestinal surgery (OPTIMISE II). |
| **IRAS Project ID:** | 209688  |
| Sponsor Amendment Notification number: | Minor amendment 7 |
| Sponsor Amendment Notification date: | 23/11/2018 |
| **Details of Chief Investigator:** |
| Name [first name and surname] | Rupert Pearse |
| Address: | Adult Critical Care UnitRoyal London HospitalWhitechapelLondonUnited Kingdom |
| Postcode: | E1 1BB |
| Contact telephone number: | +44 (0)20 3594 0351 |
| Email address: | r.pearse@qmul.ac.uk |
| **Details of Lead Sponsor:** |
| Name: | Queen Mary University London |
| Contact email address: | Research.Governance@qmul.ac.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 Management Office (QMUL, Bart’s Health NHS Trust) |

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 | Addition of sites | England | All sites or list affected sites1. [NHS Foundation Trust](https://www.bhrhospitals.nhs.uk/) – University College Hospital
 | N/A | N/A |  |
| Northern Ireland | All sites or list affected sites |
| Scotland | All sites or list affected sites |
| Wales | All sites or list affected sites |

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:* **full signature***Print name: Professor Rupert Pearse**Date:* *21st August 2018* |

|  |
| --- |
| 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:*……………………………………. |