### 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**

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| 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 5 |
| Sponsor Amendment Notification date: | 15/06/2018 |
| **Details of Chief Investigator:** | |
| Name [first name and surname] | Rupert Pearse |
| Address: | Adult Critical Care Unit  Royal London Hospital  Whitechapel  London  United 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: | sponsorsrep@bartshealth.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 Management Office (QMUL, Bart’s Health NHS Trust) |

1. **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 in wording to the NHS number to the PIS and consent form. | England | N/A | N/A | N/A |  |
| Northern Ireland | N/A |
| Scotland | NHS LOTHIAN  NHS FIFE |
| Wales | N/A |

1. **Declaration(s)**

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| --- |
| 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: 15th June 2018* |

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| 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:*……………………………………. |