### 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 3 |
| Sponsor Amendment Notification date: | 25-September-2017 |
| **Details of Chief Investigator:** |
| Name [first name and surname] | Rupert Pearse |
| Address: | 4th Floor, Room 14 Adult Critical Care Unit Royal London Hospital Whitechapel London |
| Postcode: | E1 1BB |
| Contact telephone number: | (0)20 3594 0351 |
| Email address: | r.pearse@qmul.ac.uk |
| **Details of Lead Sponsor:** |
| Name: | Queen Mary University of 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:** | Queen Mary University of London |

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 | We have made a change to the What are the possible risks and benefits of taking part? section in the Patient information sheet referring to the ‘very small risk of a minor heart attack for some patients’.The change includes the revised sentence ‘Previous research suggests that the treatment we are investigating is very safe and should benefit most patients. However we would like to collect additional safety information, and you will be closely monitored throughout the study period, to ensure the treatment is safe.’ | England | All sites  | Summary of changes to patient information sheet v3.0 18thSeptember 2017Tracked changes of the patient information sheet Clean copy of the patient information sheet  | N/Av3.0, 18th September 2017 v3.0 18th September2017 |  |
| Northern Ireland | N/A |
| Scotland | All sites  |
| Wales | All sites |
| 2 |  |  |  |  |  |
| 3 |  |  |  |  |  |
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**[Add further rows as required]**

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:* Rupert's signature*Print name:* Rupert Pearse*Date:* 25-September-2017 |

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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:*……………………………………. |