### 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: | Optimisation of Perioperative Cardiovascular Management to Improve Surgical Outcome II (OPTIMISE II) Trial |
| **IRAS Project ID:** | 209688 |
| Sponsor Amendment Notification number: | Minor Amendment 10 |
| Sponsor Amendment Notification date: | 04 June 2020 |
| **Details of Chief Investigator:** |
| Name [first name and surname] | Professor Rupert Pearse |
| Address: | Adult Critical Care Unit4th FloorRoyal London HospitalWhitechapelLondon |
| Postcode: | E1 1FR |
| Contact telephone number: | 02035940351 |
| Email address: | r.pearse@qmul.ac.uk / ruzena.uddin@qmul.ac.uk  |
| **Details of Lead Sponsor:** |
| Name: | Queen Mary University of 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)**

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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 | Restarting recruitment for the OPTIMISE II trial in the UK. | England | All sites or list affected sites  | N/A | N/A |  |
| Northern Ireland | All sites or list affected sites |
| Scotland | All sites |
| Wales |  |
| 2 |  |  |  |  |  |
| 3 |  |  |  |  |  |
| 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:* **full signature***Print name: Professor Rupert Pearse**Date: 4th June 2020* |

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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:*……………………………………. |