

From: [Nadia Yasmin Rahman](#)
To: [Rupert Pearse](#); [OPTIMISE II](#)
Cc: [Tasnin Shahid](#); [Ruzena Uddin](#); [Priyanthi Dias](#)
Subject: 209688 - NON-SA11 22.01.2020 - Acknowledgement for Barts Health NHS Trust
Date: 25 January 2021 10:59:04
Attachments: [Queen Mary University of London \(82848576\)IIS Amendment 2.doc.pdf](#)

Dear Prof Pearse,

RE: Optimisation of Peri-operative Cardiovascular Management to Improve Surgical Outcome II (OPTIMISE II) Trial: 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.

IRAS ID: 209688

Amendment: NON-SA11 22.01.2020

REC approval: N/A

HRA approval: N/A – no review required

MHRA approval: N/A

Impact

IMAGING: not applicable

PHARMACY: not applicable

PATHOLOGY: not applicable

CONTRACT AMENDMENT: fully executed version attached

Documents reviewed: All approved documents

Document	Version	Date
Amendment tool	NON-SA11	22 January 2021
Protocol – clean	2.0	08 December 2020
Protocol - tracked	V1.1	08 December 2020

This amendment has been reviewed for Barts Health NHS Trust and can be implemented.

Please contact us using the details below if you require any further information.

Best wishes,

Nadia Rahman

Research Management & Governance Officer
Barts Health NHS Trust/Queen Mary University of London

From: Tasnin Shahid <t.shahid@qmul.ac.uk>
Date: Friday, 22 January 2021 at 14:59
To: Nadia Yasmin Rahman <nadia.rahman@qmul.ac.uk>
Cc: OPTIMISE II <admin@optimiseii.org>, Ruzena Uddin <ruzena.uddin@qmul.ac.uk>, Priyanthi Dias <p.dias@qmul.ac.uk>
Subject: FW: IRAS 209688. Amendment

Dear Nadia,

Please see the email below stating that no further regulatory review is required for the OPTIMISE II (IRAS 209688) non-substantial amendment 11.

Best wishes,

Tasnin

Tasnin Shahid
Research Technician

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Website – <https://www.qmul.ac.uk/ccpmg/>

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From: New IRAS Dev <no-reply-iras@hra.nhs.uk>

Sent: 22 January 2021 14:50

To: Tasnin Shahid <t.shahid@qmul.ac.uk>

Subject: IRAS 209688. Amendment

IRAS Project ID: 209688
Sponsor amendment reference: NON-SA 11

Thank you for submitting your study amendment. In accordance with the outcome of your completed amendment tool, this amendment requires no further regulatory review. Please now share this amendment with your UK research sites, in accordance with the instructions in your completed amendment tool.

For studies with more than one UK research site, your amendment will now be automatically shared with the R&D offices of any NHS/HSC research sites in Scotland and Northern Ireland, but you should share the amendment by email directly with those Research team/s.

For all NHS research sites in England and Wales, please now share this amendment by email directly with those sites, including both the R&D offices and research teams.

Do not reply to this email as this is an unmonitored address and replies to this email cannot be responded to or read.

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