**From:** ADAMS, Catherine (HEALTH RESEARCH AUTHORITY)
**Sent:** 19 July 2017 12:54
**To:** MOONESINGHE, Ramani (NHS ENGLAND); Perioperative Quality Improvement Programme
**Cc:** rand.d@uclh.nhs.uk

**Subject:** RE: IRAS 215928.Perioperative Quality Improvement Programme: Patient Study 16 LO 1827 Amendment Assessment Outcome

Dear Dr Moonesinghe,

Further to the below, I am pleased to confirm that HRA Approval has been issued for the referenced amendment, following assessment against the HRA criteria and standards.

The sponsor should now work collaboratively with participating NHS organisations in England to implement the amendment as per the below categorisation information. This email may be provided by the sponsor to participating organisations in England to evidence that the amendment has HRA Approval.

Please contact hra.amendments@nhs.net for any queries relating to the assessment of this amendment.

Best Wishes

Catherine Adams| Senior Assessor

**Health Research Authority**

Room 002

TEDCO Enterprise Park

Jarrow

NE32 3DT

E: Catherine.adams8@nhs.net| 02079722503

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**From:** nrescommittee.secoast-surrey@nhs.net [mailto:nrescommittee.secoast-surrey@nhs.net]
**Sent:** 26 June 2017 02:56
**To:** ramani.moonesinghe@nhs.net; rand.d@uclh.nhs.uk
**Cc:** rand.d@uclh.nhs.uk
**Subject:** IRAS 215928. Confirmation of REC Validation and Categorisation of Amendment

## Amendment Confirmation of REC Validation, Categorisation and Implementation Information

Dear Dr Moonesinghe,

Thank you for submitting an amendment to your project. Please find attached a copy of the REC validation letter for the submitted amendment.

If you have participating NHS/HSC organisations in any other UK nations we will forward the information to the relevant national coordinating function(s).

Please note that you may only implement changes described in the amendment notice.

**What Happens Next?**

When available, please forward any other regulatory approvals that are expected for this amendment to hra.amendments@nhs.net. However, you do not need to forward the REC favourable opinion as we will be able to access this through our systems.

**Information Specific to Participating NHS Organisations in England**

1. **1.** You should now share your notice of amendment and, if applicable, amended documents, together with this email, with all participating NHS organisations in England. In doing so, you should include the NHS R&D Office, LCRN (where applicable) as well as the local research team. A template email to notify participating NHS organisations in England is provided on the HRA website.

2. 2. The participating NHS organisations in England should prepare to implement this amendment.

3. 3. **Your amendment will be reviewed by the REC, as per the attached letter. In parallel to this, an assessment against** HRA standards will take place.

4. **4.** Once the REC Favourable Opinion is issued, any other regulatory approvals are in place and the HRA assessment has been successfully completed, you will receive an email confirming that your amendment has HRA Approval.

5. 5. You may implement your amendment at all participating NHS organisations in England 35 calendar days from the day on which you provide the organisations with this email and your amended documents (or as soon as the participating NHS organisation confirm that you may implement, if sooner), so long as you have HRA Approval for your amendment by this date. **NHS organisations do not have to confirm they are happy with the amendment.** If HRA Approval is issued subsequent to this date, you may implement following HRA Approval.

6. **6.** You may not implement the amendment at any participating NHS organisations in England that requests additional time to assess, until it confirms that it has concluded its assessment.

7. 7. You may not implement at any participating NHS organisation in England that declines to implement the amendment.

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|---|---|
| **IRAS Project ID:** | **215928** |
| **REC Reference:** | **16/LO/1827** |
| **Short Study Title:** | **Perioperative Quality Improvement Programme: Patient Study** |
| **Date complete amendment submission received:** | **23 June 2017** |
| **Sponsor Amendment Reference Number:** | **2.0** |
| **Sponsor Amendment Date:** | **28 March 2017** |
| **Amendment Type:** | **Substantial** |
| **Outcome of HRA Assessment:** | **HRA Approval for the amendment is pending - the HRA will separately confirm HRA Approval for the amendment by email.** |
| **Implementation date in NHS organisations in England** | **35 days from date of amendment information together with this email, is supplied to participating organisations (provided HRA Approval for the amendment is in place and the above conditions are met).** |
| **Amendment Category (For NHS/HSC R&D Office information)** | **A** |

If you have any questions about the ethical review of this amendment, please do not hesitate to contact me.

If you have any questions relating to the wider HRA approval process, please direct these to hra.approval@nhs.net

If you have any questions relating this amendment in one of the devolved administrations, please direct these to the relevant national coordinating function.

Additional information on the management of amendments can be found in the IRAS guidance.

Please do not hesitate to contact me if you require further information.

Kind regards,

Raj Khullar

REC Manager

Health Research Authority
HRA, Ground Floor, Skipton House, 80 London Road, London, SE1 6LH
E: hra.amendments@nhs.net

www.hra.nhs.uk

The HRA is keen to know your views on the service you received – our short feedback form is available here