

## Amendment Categorisation and Implementation Information

Dear Dr Moonesinghe,

Thank you for submitting an amendment to your project.

If you have participating NHS/HSC organisations in any other UK nations that are affected by this amendment 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?

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

1. **This email also constitutes HRA Approval for the amendment**, and you should not expect anything further from the HRA.
2. You may implement this amendment immediately.
3. You should ensure that participating NHS organisations in England are informed of this amendment. In doing so, you should include the [NHS R&D Office](#), [LCRN](#) (where applicable) as well as the local research team.
4. Participating NHS organisations in England should prepare to implement this amendment, where expected.

#### Information Specific to Participating NHS/HSC Organisations in Northern Ireland, Scotland and/or Wales

1. **You may implement this amendment immediately**
2. You do not need to inform the R&D offices, as we have separately made it available via their national coordinating functions.
3. Participating NHS/HSC organisations should prepare to implement this amendment, where expected.

<b>IRAS Project ID:</b>	215928
<b>Short Study Title:</b>	Perioperative Quality Improvement Programme: Patient Study
<b>Date complete amendment submission received:</b>	21/02/2018
<b>Amendment No./ Sponsor Ref:</b>	Addition of new sites & Consent Form updated
<b>Amendment Date:</b>	16 February 2018
<b>Amendment Type:</b>	Non-substantial
<b>Outcome of HRA Assessment</b>	<b>This email also constitutes HRA Approval for the amendment</b> , and you should not expect anything further from the HRA.
<b>For NHS/HSC R&amp;D Office information</b>	
<b>Amendment Category</b>	C

## Additional Sites:

<b>IRAS Project ID:</b>	215928
<b>Short Study Title:</b>	Perioperative Quality Improvement Programme: Patient Study
<b>Date complete amendment submission received:</b>	22/02/2018
<b>Sponsor Amendment Reference Number:</b>	Addition of new sites & Consent update - 16/02/2018
<b>Sponsor Amendment Date:</b>	16 February 2018
<b>Amendment Type:</b>	Non-substantial
<b>For new sites in Northern Ireland, Scotland and/or Wales only:</b>	Please start to set up your new sites. Sites may not open until NHS management permission is in place.
<b>For new sites in England only:</b>	<p>For studies which already have HRA Approval: <b>This email also constitutes HRA Approval for the amendment, and you should not expect anything further from the HRA.</b> Please start to set up your new sites. Sites may not open until the site has confirmed capacity and capability (where applicable).</p> <p>For studies which do not yet have HRA Approval: HRA Approval is pending and you will receive confirmation of HRA Approval. You can start the process of setting up the new site but cannot open the study at the site until HRA Approval is in place and the site has confirmed capacity and capability (where applicable).</p>

If you have any questions relating to setting up sites in England, please direct these to [hra.approval@nhs.net](mailto:hra.approval@nhs.net).

If you have any questions relating to setting up sites in Northern Ireland, Scotland or Wales, please direct these to the relevant [national coordinating function](#).

**Note:** you may only implement changes described in the amendment notice.

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

Kind regards

**Mr Ali Hussain**

**Amendments Co-ordinator**

**Health Research Authority**

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E. [hra.amendments@nhs.net](mailto:hra.amendments@nhs.net)

W. [www.hra.nhs.uk](http://www.hra.nhs.uk)

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